MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

MEDICOPLAST International GmbH
Heusweilerstr. 100
66557 Illingen
Germany

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-05-25**
Expiry date: **2024-05-27**

Report No.: 1189FS19F
Process No.: QS – 1189
Certificate No.: 1189GB415210525A

Hamburg, 2021-05-25

MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 1189
Certificate No.: 1189GB415210525A

List of products / product categories included in the scope of certificate

- **Female-catheters**
- **Nelaton-catheters**
- **Tiemann-catheters**
- **Atraumatische Katheter**
- **Drainage bagy**
- **Rectal tubes**
- **Suction sets**
- **Suction catheters**
- **Suction cannulas**
- **Suction mucus extractor**
- **Tubes and accessoeries**
  - **Tube sections**
  - **Clamps**
  - **Connectors**
  - **Valves**
- **Tracheal tubes and accessories**
- **Tracheal cannulas and accessories**
- **Cord clamps**
- **Redon systems and accessories**
- **Redon drainages and accessories**
- **Jet catheter and accessories**
- **Biopsy attachment (needle guide sleeve)**
- **Sterile covers**

– End of list –

mdc	**Transfer Agreement for Surveillance of Legacy Devices**	11323 003/08.2023

This agreement specifies the terms of the transfer of the appropriate surveillance activities according to Article 120 (3e) of Regulation (EU) (EU) 2017/745[1] in respect of legacy devices covered by a certificate issued in accordance with Directive 93/42/EEC between the manufacturer

Medicoplast International GmbH
Heuswellerstraße 100
66557 Illingen

(in the following "CERTIFICATION HOLDER"),

his Notified Body under Directive 93/42/EEC with the identification number **0482**

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg

(in the following "OUTGOING NB")

and his Notified Body under Regulation (EU) 2017/745 with the identification number **0483**

mdc medical device certification GmbH
Kriegerstraße 6
70191 Stuttgart

(in the following "INCOMING NB")

The parties have concluded the following under the TRANSFER DATE effective on **[2024-07-01]**:

§ 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by OUTGOING NB in accordance with Directive 93/42/EEC that is valid or to be considered to be valid by virtue of paragraph 2 of Article 120 Regulation (EU) 2017/745 covering devices which are placed on the market after date of application of the Regulation (EU) 2017/745 until the date set out in paragraph 3a of Article 120 of this Regulation (hereinafter referred to as "legacy device[2]") that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 120 (3e) of Regulation (EU) 2017/745 (hereinafter referred to as "appropriate surveillance"), and intends that this appropriate surveillance in respect of that legacy devices are in future carried out by the INCOMING NB. Appropriate surveillance[3] can include for example documentation review, audits or other kinds of assessments performed by a notified body in respect of a legacy device (see § 6 (1)) as part of CERTIFICATION HOLDER's previous conformity assessment procedure under Directive 93/42/EEC. Certification is a valid confirmation in the form of a certification document, in accordance this Directive, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by OUTGOING NB[4].

2. The legacy devices that the OUTGOING NB issued a certification for and which are subject to transferred appropriate surveillance to the INCOMING NB (hereinafter referred to as "legacy devices subject to transfer of appropriate surveillance"), and the agreed date on which any review activities by the INCOMING NB in accordance with § 4 are to be completed and from which any surveillance activities by the INCOMING NB are to be carried out and the responsibility for the appropriate surveillance assumed by INCOMING NB (hereinafter referred to as "TRANSFER DATE"), are specified in Appendix 1. The TRANSFER DATE shall not exceed 26 September 2024.

3. Appropriate surveillance may be transferred only in respect of a legacy device for as long as it is included in the scope of a certification considered as valid in accordance with Article 120 paragraph 2 or Regulation (EU) 2017/745 and issued by an OUTGOING NB covered with the respective designation/notification valid at the time when this certification was issued.
   Certification, which is suspended or temporarily restricted for the relevant legacy device may not be accepted for transfer of appropriate surveillance in respect of that device, but it is up to the INCOMING NB's decision and subject to the assessment prior to transfer in accordance with § 4.

[1] As amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023
[2] As per MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021)
[3] MDCG 2022-4 Rev. 1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR regarding devices covered by certificates according to the MDD or the AIMDD
Examples of surveillance activities (non-exhaustive): QMS audits, focused audits (e.g. sterilization, microbiology, supplier etc.), unannounced audits, for cause audits, change notification assessment, e.g. changes which are considered not to be significant as per Art. 120.3, Vigilance handling, appeals, complaints, authority notes (e.g. CEFs, classification disputes/decisions), certificate actions (withdrawal, suspension, re-instatement, cancellations), notification to national authorities
[4] According MDCG 2020-3 rev 1 section 4.3

Certification, which is withdrawn or otherwise invalidated prior to TRANSFER DATE is not subject to transfer of appropriate surveillance in respect of that device.

4. The transition of appropriate surveillance in respect of a legacy device from OUTGOING NB to INCOMING NB by way of transfer means that the INCOMING NB, when assuming these activities, takes into account, according to its procedures, the activities of the OUTGOING NB in respect of that device. The INCOMING NB has to ensure that adequate rights and obligations are agreed with CERTIFICATION HOLDER on a contractual basis to ensure the performance of appropriate surveillance incl. the right to suspend, restrict, withdraw etc. concerned certificates that issued the OUTGOING NB and are subject to this agreement; this includes as well auditing rights e.g. on the premisses of CERTIFICATE HOLDER and his subcontractors etc.

5. The appropriate surveillance subject to transfer performed by OUTGOING NB prior to transfer date is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and OUTGOING NB. Following the transfer, the OUTGOING NB and the manufacturer shall amend or terminate (whatever is applicable) their certification agreements in respect of legacy devices subject to transfer of appropriate surveillance.

6. This Agreement specifies the terms and modalities for the transfer of appropriate surveillance from an OUTGOING NB to an INCOMING NB in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities between the OUTGOING NB and the INCOMING NB in accordance with this Regulation and requirements. The appropriate surveillance should be transferred from OUTGOING NB to INCOMING NB in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

§ 2 Agreement conclusion and amendments

The transfer of appropriate surveillance in accordance with this Agreement shall be accomplished in the following steps:

1. (Step1): The transfer process starts with the conclusion of this Agreement, including Appendix 1. Specification of TRANSFER DATE in Appendix 1 and the complete Appendix 2 are optional in this step and may be provided in Step 2.

   a. CERTIFICATION HOLDER signs the Agreement. The Agreement shall include Appendix 1, and certificates listed in Appendix 1 shall be attached. The Agreement may additionally include Appendix 2. CERTIFICATION HOLDER then forwards the Agreement to INCOMING NB.

   b. INCOMING NB verifies and countersigns the Agreement and returns it to CERTIFICATION HOLDER. At this time, any unclarities in the description of appropriate surveillance subject to transfer shall be resolved between the INCOMING NB and CERTIFICATION HOLDER, and corrections to the Agreement made, as necessary. The CERTIFICATION HOLDER then forwards the Agreement to the OUTGOING NB.

   c. OUTGOING NB verifies and countersigns the Agreement, and forwards it to both CERTIFICATION HOLDER and INCOMING NB.

2. (Step 2): As soon as the INCOMING NB's activities have progressed sufficiently in order to specify the TRANSFER DATE and any other information in Appendices 1 and 2, or if it becomes clear that any of this information is no longer correct, the information in Appendices 1 and 2 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 3 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

If the involvement of the OUTGOING NB in this Agreement is not practicable[5], only in those cases, the Agreement shall be considered valid with only two signatures. In those cases the obligations of the OUTGOING NB in accordance with this Agreement should be fulfilled by CERTIFICATION HOLDER as far as possible.

[5] Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023) Question 14, Answer: *In the third subparagraph of Article 120(3e) MDR, the limitation that requires the notified body that issued the relevant certificate under the MDD/AIMDD to sign the arrangement for the transfer of the appropriate surveillance where practicable takes into account that there might be cases when this notified body could be unable to sign the contract, e.g. termination of business. In any case, it is required to have in place a written agreement between the manufacturer and the MDR notified body to specify the*

In this case, it is the responsibility of the INCOMING NB to decide whether the transition of appropriate surveillance by way of transfer is appropriate, what additional assessment activities are needed prior to assuming the responsibility for the appropriate surveillance, and whether they are sufficient to maintain the appropriate surveillance in the way to keep the certification valid in the meaning of § 3 (1).

§ 3 Validity of certification and notified body surveillance activities for the legacy devices subject to transfer of appropriate surveillance

1. CERTIFICATION HOLDER shall comply with the requirements of Article 120 of Regulation (EU) 2017/745 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.

2. OUTGOING NB shall not suspend or withdraw the CERTIFICATION HOLDER's certification, in respect of legacy devices subject to transfer of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the CERTIFICATION HOLDER is transferring the appropriate surveillance to the INCOMING NB. The rights of the OUTGOING NB to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected until the date of transfer. Followed by the transfer, contractual agreements shall be amended respectively or terminated (whatever is applicable) (see § 1 (5)).

3. Appropriate surveillance, performed by OUTGOING NB, will be fully transferred in respect of the legacy devices specified in Appendix 1, i.e. equivalent appropriate surveillance will be commenced by the INCOMING NB, on the TRANSFER DATE.

4. CERTIFICATION HOLDER shall continue to apply the notified body identification number of the OUTGOING NB to legacy devices subject to transfer of appropriate surveillance, if not otherwise agreed as per Appendix 2.

5. If agreed as per Appendix 2, the change of notified body identification number from OUTGOING NB to INCOMING NB number shall be documented for devices in the scope of certification the legacy devices subject to transfer of appropriate surveillance on a product-by-product basis during the agreed TRANSITION SELL-OFF PERIOD. The change of notified body number for each device (catalogue number) shall be documented and fixed to a specific serial number or lot number. CERTIFICATION HOLDER commits to document this change for each device (catalogue number) in Appendix 2 and make this information available upon the request of the INCOMING NB.

6. CERTIFICATION HOLDER commits to inform the OUTGOING NB and INCOMING NB in writing of the dates when the placing on the market of the legacy devices subject to transfer of appropriate surveillance under the notified body surveillance activities of the OUTGOING NB has been discontinued within 30 days after discontinuation.

§ 4 Assessment prior to transfer

INCOMING NB has the full responsibility and authority for the decision, based on information provided by CERTIFICATION HOLDER, OUTGOING NB, and publicly available information, regarding the extent of its assessment prior to TRANSFER DATE. In all cases, prior to transferring the appropriate surveillance on the agreed TRANSFER DATE, INCOMING NB shall ensure that there is an overview of all required assessment activities and their individual status of completion. Any identified unresolved concerns, findings, non-conformities, surveillance notes, etc. shall be addressed based on their criticality in the scheduling/planning of the consecutive appropriate surveillance activities by the INCOMING NB.

§ 5 Confidentiality and obligation to provide information

In order to allow the INCOMING NB to complete the assessment prior to transfer according to § 4 and to perform the appropriate surveillance after the TRANSFER DATE (see § 1):

1. CERTIFICATION HOLDER commits to provide on request to the INCOMING NB any relevant information relating to the assessment and certification of a legacy device subject to transfer of appropriate surveillance. Such a request may include valid certificate(s) for the legacy device concerned by the transfer of appropriate surveillance, assessment reports, consultation reports issued by authorities, non-

arrangements concerning the appropriate surveillance to be performed by the latter even if the notified body that issued the MDD/AIMDD certificates cannot be involved.

➔ "Practicable" means that the outgoing NB cannot be reached any longer.

conformities, corrective actions, complaint records, vigilance records and any other relevant records or information of OUTGOING NB or even another previous notified body.

2. CERTIFICATION HOLDER approves that OUTGOING NB may disclose, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1), related to the assessment and certification of the legacy devices subject to transfer of appropriate surveillance, to INCOMING NB, to enable any direct communication between OUTGOING NB and INCOMING NB that may be required.

3. CERTIFICATION HOLDER understands that INCOMING NB will contact OUTGOING NB to request information relating to the legacy devices subject to transfer of appropriate surveillance.

4. OUTGOING NB understands and approves that CERTIFICATION HOLDER may disclose to INCOMING NB, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1.) related to the legacy device subject to transfer of appropriate surveillance.

5. CERTIFICATION HOLDER commits to submit copies of the written confirmation of the transferred appropriate surveillance issued by INCOMING NB to OUTGOING NB without undue delay, at the latest within 30 calendar days of the TRANSFER DATE.

6. CERTIFICATION HOLDER confirms, for each legacy device subject to modification of the labelling by changing the number of the OUTGOING NB to the number of the INCOMING NB, the last serial number or lot number under the notified body appropriate surveillance of the OUTGOING NB, in accordance with Appendix 2. If this information is not yet known on the date when this Agreement comes into force, or changes occur after the date when this Agreement comes into force, CERTIFICATION HOLDER shall submit to OUTGOING NB and INCOMING NB the last serial number or lot number under the notified body oversight of the OUTGOING NB within 30 calendar days of it becoming known or changed. Together with the actual transfer date, this will allow traceability of devices, and responsibilities regarding appropriate surveillance.

7. The CERTIFICATION HOLDER and the INCOMING NB take care that the OUTGOING NB is informed about the following issues with respect to devices placed on the market with the identification number of the OUTGOING NB:
   a. Vigilance cases (reportable incidents and Field Safety Corrective Actions)
   b. Inspections, inquiries and other activities by Competent Authorities
   c. Misuse of certificates or CE mark
   d. Obstacles encountered regarding performance of adequate surveillance

   The INCOMING NB may inform the OUTGOING NB about additional issues in case there is a justified reason.

§ 6 Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the notified body appropriate surveillance activities[6] for the legacy device subject to transferred appropriate surveillance, including
   a. any continuing conformity assessment activities
   b. surveillance activities
   c. post-certification monitoring and the assessment of the CERTIFICATION HOLDER's vigilance system with respect to the legacy device manufactured which is under the transferred appropriate surveillance, including NB's involvement in vigilance case assessments
   d. communication with authorities in respect of the legacy device
   e. continued assessment of changes to the device
   f. continued assessment of changes for the related quality management system
   g. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device7 including restriction, suspension and withdrawal of the validity of certification for the legacy device.

[6] General applicable document MDCG 2022-4, Rev. 1 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD
[7] MDCG 2020-3 Rev.1, Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD - **Section 4.3**

2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about transfer of surveillance to INCOMING NB.

3. Changes on the device list as per Appendix 1 of this Agreement: based on MDCG 2020-3, rev. 1, section 4.3.2.3, the following changes are considered as "non-significant change" towards MDR, Art. 120(3c):
   Change in Specification/Labelling:
   - change within the currently certified range (more narrow or detailed information), new article inside certified worst case or accepted bracket validations such as:
     - new screw variant within current range of lengths and diameter;
     - new catheter variant, with length and diameter within current range and worst case in sterilisation performance;
     - new stent lengths which are intermediate between the previously certified stent lengths.

In respect of this agreement, it means that after the TRANSFER DATE additional devices might be added under the scope of the MDD certificate without acknowledgement by the OUTGOING NB initially issued the certificate.
The addition of such additional devices is considered only possible if for the same devices or its substitute device[8] a formal application has been lodged with the MDR Notified Body and written agreement for the MDR conformity assessment conducted.
The responsibility and liability towards the initial certification of the certified range and accepted bracket validations lies with the OUTGOING NB.
The responsibility and liability towards the assessment of the appropriateness of the change under Art. 120, and further appropriate surveillance including individual device traceability along the new conditions lies with the INCOMING NB.
In terms of CExxxx marking, the CERTIFICATION HOLDER and INCOMING NB may decide to agree on the labelling of these specific "legacy devices" indicating the number of the MDR Notified Body, instead of the original MDD certificate issuing OUTGOING NB.

§ 7 Settlement and property rights

1. If not agreed otherwise, CERTIFICATION HOLDER shall settle, in respect of the legacy device subject to transfer of appropriate surveillance, all outstanding invoices with OUTGOING NB and, as applicable, any affiliate of OUTGOING NB supplying notified body certification services under the control of OUTGOING NB. Furthermore, the CERTIFICATION HOLDER agrees that all services related to this transfer performed by the OUTGOING NB are invoiced by the OUTGOING NB to the CERTIFICATION HOLDER according to the existing or previous contractual arrangements regarding certification under Directive 93/42/EEC independently from any termination.

2. All documents provided by OUTGOING NB and all documents (assessment reports, certificates, etc.) which were generated by OUTGOING NB for the execution of certification, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the OUTGOING NB.

3. All documents provided by INCOMING NB and all documents (assessment reports, etc.) which were generated by INCOMMING NB for the performance of appropriate surveillance, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the INCOMING NB.

§ 8 Miscellaneous

1. (Severability). Should any individual provision of this Agreement or any part of any provision be or become void and/or unenforceable, the validity of the other provisions of the Agreement shall in no way be affected. In such case, the CERTIFICATION HOLDER, OUTGOING NB an INCOMING NB shall replace, by way of an amendment or change to this Agreement, the void and/or unenforceable provisions with permissible provisions that fulfil the original intent of the void and/or unenforceable provision to the closest possible extent.

2. (Written form). Any amendments or changes to this Agreement shall be made in writing. This applies especially to any change to an agreed TRANSFER DATE, which shall be agreed-upon in writing, by way of an addendum to this Agreement, between the involved parties prior to the respective previously agreed TRANSFER DATE. The form provided in Appendix 3 should be used for such addendum.

[8] Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Question 10. What is the meaning of "device intended to substitute that device"

3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially INCOMING NB shall assume full responsibility for contracted surveillance activities, incl. the assessment of the CERTIFICATION HOLDER's vigilance system with respect to all devices included in the scope of certification subject to transferred surveillance. However, according to Art. 120 (3e) subparagraph 3 MDR the INCOMMING NB shall not be responsible for conformity assessment activities incl. previous surveillance activities carried out by OUTGOING NB as the notified body that issued the certificate(s).
   Especially OUTGOING NB shall assume full responsibility for the certification subject to transferred surveillance, including all conformity assessment activities incl. previous surveillance activities prior to TRANSFER DATE.
   In particular, the OUTGOING NB recognises its responsibility for any act or omission accomplished prior to TRANSFER DATE. The CERTIFICATION HOLDER commits not to hold the INCOMING NB responsible for these acts or omissions.

4. (Jurisdiction). Unless otherwise agreed, this Agreement shall be governed by, and interpreted in accordance with the substantive laws of the country of INCOMING NB exclusive of any rules with respect to conflicts of laws.

5. (Disputes). Disputes arising in connection with this Agreement shall be settled as follows:

   a. Disputes between CERTIFICATION HOLDER and INCOMING NB shall be settled by CERTIFICATION HOLDER and INCOMING NB under the provisions of their certification agreement.

   b. Disputes between CERTIFICATION HOLDER and OUTGOING NB shall be settled by CERTIFICATION HOLDER and OUTGOING NB under the provisions with regard to appeals of their certification agreement.

6. (Coming into force) This Agreement comes into force on the date the last of the three involved parties, INCOMING NB, OUTGOING NB, and CERTIFICATION HOLDER has signed this Agreement (also see § 6.3).

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Legally Binding Signature CERTIFICATION HOLDER	Legally Binding Signature INCOMING NB	Legally Binding Signature OUTGOING NB
Illingen 05.06.2024	11. JUNI 2024	Document signed by: Klaus-Dieter Ziel, DNV MEDCERT GmbH on: 2024/07/01 10:55
Nico Binkle **Head of Business Develop. / RA**	Harald Rentschler General Manager	Klaus-Dieter Ziel Geschäftsführer

Attachments

- ☒ Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- ☒ Copies of certificates specified in Appendix 1 (mandatory)
- ☒ Appendix 2 – Transition provisions (optional)
- ☐ Appendix 3 – Addendum form to specify or amend Appendices 1 and 2 (optional)

Overview of provisions covered or taken into consideration in this Agreement:

1. Articles 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC., as amended by Regulation (EU) 2023/607.

2. MDCG 2020-3 Rev.1, Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

3. MDCG 2022-4 Rev.1, Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

4. MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021)

5. European Commission, Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (July 2023)

Appendix 1 – Legacy devices subject to transfer of appropriate surveillance

Devices covered by this agreement and for which the INCOMING NB is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive

MDD Device name or REF	MDD Certificate Reference of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Tracheostomie Tubus mit Cuff mit Armierung verschiebbare Halteplatte Mediland 4061961A2BTK0008J4	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomie Tubus ohne Cuff mit Armierung verschiebbare Halteplatte Mediland 4061961A2BTK0007J2	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomie Tubus Innenkanüle Mediland 4061961A2BTK0002BK	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomie Tubus Bisalski Innenkanüle Mediland 4061961A2BTKB002FA	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomie Tubus Bisalski Sprechventil Mediland 4061961A2BTKB003FC	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomie Tubus Bisalski ohne cuff ohne armierung feste Halteplatte Teleflex 4061961A2BTKB004FE	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Tracheostomie Tubus Bisalski ohne cuff ohne armierung feste Halteplatte 4061961A2BTKB001F8	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheostomietubus Bulk unsteril 4061961A2UTK0001ML	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Uretersplint Steuerbar 4061961U2BUK0005SJ	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Uretersplint Steuerbar Mediland 4061961U2BUK0006SL	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Uretersplint Mediland 4061961U2BUK0001SA	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Uretersplint 4061961U2BUK0003SE	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nephrostomy Set 4061961U2BNSK004Y3	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Nephrostomie-Dilatations-Set Teleflex 4061961U2BNSK005Y5	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ureterokutaneostomiekatheter 4061961U2BUKS001ZQ	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
DLTK links Mediland 4061961A2BTK0009BZ	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
DLTK rechts Mediland 4061961A2BTK0008BX	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Endotrachealtuben ohne Cuff 4061961A2AETT001FM	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Real Tracheal tuben oral 4061961A2ARTT0001XS	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Real Tracheal tuben nasal 4061961A2ARTT0002XU	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Endotrachealtuben mit Cuff 4061961A2AETT002FP	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Spiraltuben Endotracheal mit Cuff 4061961A2ASTT0001YB	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Spiraltuben Endotracheal ohne Cuff 4061961A2ASTT0002YD	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Spiraltuben Endotracheal mit Cuff Mediland 4061961A2ASTT0003YF	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tubuswechsler Mediland 4061961A2ATW0001F4	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Laryngektomietubus Mediland 4061961A2ATK0001AY	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Real Tracheal tuben oral, Mediland 4061961A2ARTT0003XW	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Real Tracheal tuben nasal, Mediland 4061961A2ARTT0004XY	1189DE410200616 CE0482	☒ N/A or	☐ 31 December 2027		

		☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2028		
Absaug Katheter für Tracheostomie 4061961A2AAK000ZL	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaug Katheter Atemtrakt mit Saugregulierung 4061961A2AAK00023B	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaug Katheter Atemtrakt ohne Saugregulierung 4061961A2AAK00039J	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugatheter Euromedis 4061961A2AAK00063K	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugkatheter Asid Bonz 4061961A2AAK00053H	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugkatheter Megro 4061961A2AAK00043F	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaug Katheter Bronchoskop ohne Saugregulierung 4061961A2AAK00033D	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Absaugkatheter Mediland 4061961A2AAK00083P	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaug Katheter für Tracheostomie mit Saugregulierung 4061961A2AAK00103A	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugkatheter AUT 4061961A2AAK00093R	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoffkatheter mit Kompresse 4061961A2ASK0002AM	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoffverbindungsschlauch 4061961A2ASK0003AP	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoffkatheter ohne Kompresse 4061961A2ASK0007AX	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoff Brille 4061961A2ASK0004AR	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Sauerstoffkatheter mit Kompresse Megro 4061961A2ASK0005AT	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoffkatheter AUT 4061961A2ASK0008AZ	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoffverbindungsschlauch AUT 4061961A2ASK0009B3	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoff-Verbindungsschlauch Mediland 4061961A2ASK0001AK	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Sauerstoff-Verbindungsschlauch Teleflex 4061961A2ASK0006AV	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Bronchial Doppellumen Tubus, rechts 4061961A2ABDLT001MP	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Bronchial Doppellumen Tubus, rechts, Mediland 4061961A2ABDLT004MV	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Bronchial Doppellumen Tubus, links **4061961A2ABDLT002MR**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Bronchial Doppellumen Tubus, links, Mediland **4061961A2ABDLT006MZ**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
BDLT Zubehör **4061961A2ABDLT003MT**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
BDLT Zubehör, Mediland **4061961A2ABDLT005MX**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Bronchusblocker Mediland **4061961A2ABB0001YG**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Zubehör Bronchusblocker Winkelstück Mediland **4061961A2ABB0002YJ**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Spiraltubus Mediland **4061961A2ABT000385HE**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugschlauch **4061961C2ASGK003GF**	1189DE410200616 CE0482	☒ N/A or	☐ 31 December 2027		

		☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2028		
Saugschlauch AUT 4061961C2ASGK006GM	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugschlauch bulk unsteril 4061961C2ASGK002GD	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugsatz bulk unsteril 4061961C2AAS00037K	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugschlauch bulk unsteril AUT 4061961C2ASGK005GK	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugsatz 4061961C2AAS00017F	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugkanüle unsteril 4061961C2ASGK008GR	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugkanülen und -rohe 4061961C2ASGK001GB	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Saugkanülen und -rohe AUT4061961C2ASGK007GP	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Saugkanülen mit Handgriff 4061961C2ASGK004GH	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Wundrandschutzfolie 4061961D2AWS0001H4	**1189DE414210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Duodenalsonde, PVC, ohne x-ray 4061961G2aDS0002RX	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Duodenalsonde AUT 4061961G2aDS0005S5	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Duodenalsonde, PVC, mit x-ray 4061961G2ADS0003BN	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Duodenalsonde, PUR, mit x-ray 4061961G2ADS0004BQ	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Magensonden und -Schläuche PVC 4061961G2AMS0001F7	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Magensonden und -Schläuche PUR 4061961G2AMS0002F9	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Magensonden und -Schläuche PVC, x-ray 4061961G2AMS0003FB	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Magensonden und -Schläuche, unsteril 4061961G2AMS0004FD	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nährsonde PVC, x-ray 4061961G2ANS0002FN	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nährsonde PUR, x-ray 4061961G2ANS0001FL	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nährsonde AUT 4061961G2ANS0003FQ	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Ösophaguskatheter **4061961G2AOE0001B7**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Redon Nadeln **4061961R2ADK0002GR**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen unsteril **4061961R2ADK0003GT**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen AUT **4061961R2ADK0004GV**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen Ecomed **4061961R2ADK0010GQ**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen **4061961R2ADK0001GP**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagesysteme mit Redonflasche **4061961R2ADK0011GS**	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagesysteme mit Drainagebeutel **4061961R2ADK0012GU**	1189DE410200616 CE0482	☒ N/A or	☐ 31 December 2027		

		☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2028		
Drainagesysteme AUT 4061961R2ADK0008H5	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagesysteme 4061961R2ADK0005GX	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Seldinger Pleura Drainage 4061961R2APS0002QD	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Pleura Drainage 4061961R2APS0001QB	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Thorax Drainage mit Trokar 4061961R2ATD0002LU	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Thorax Drainage 4061961R2ATD0001LS	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen Euromedis 4061961R2ADK0007H3	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Hyperthermiekatheter Mediland 4061961U2AHTK001V9	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Couvalairespitze und Ballon 4061961U2ABK0002J4	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Dufourspitze und Ballon 4061961U2ABK0003J6	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nephrostomy Punktionsnadel Teleflex 4061961U2ADT0001MX	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Dilatator Teleflex 4061961U2BNSK006Y7	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ureterkatheter und -splinte Mono J 4061961U2AUK0003RV	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ureterkatheter und -splinte Mono J PVC 4061961U2AUK0006S3	1189DE410200616 CE0482	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Ureterkatheter und -splinte Mono J mit Olivspitze 4061961U2AUK0005RZ	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Ureterkatheter Mediland 4061961U2AUK0001RR	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Absaugsatz AUT 4061961C2AAS00047M	**1189DE410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Wechselmandrin, Obturator Tracheostomie Tuben 4061961A1SET0003H3	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Wechselmandrin, Obturator 4061961A1SET0001GX	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Wechselmandrin, Obturator Mediland 4061961A1SET0002GZ	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Wechselmandrin, Obturator Mediland, unsteril 4061961A1U00001GZ3V	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Nasopharyngeal Tuben 4061961A1SNPT001SV	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nasopharyngeal Tuben mediland 4061961A1SNPT002SX	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheal Saugset 4061961A1STS00001WD	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheal Saugset Teleflex 4061961A1STS00002WF	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Tracheal Saugset AUT 4061961A1STS00003WH	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
BAL-Katheter 4061961A1SBAL001F4	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Abdecktuch 4061961D1SAT0001HG	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Injektionskatheter 4061961D2AIK00018N	1189DE415210525A CE0482	☒ N/A or	☐ 31 December 2027		

		☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2028		
Darmrohr 4061961G1SDR0002L8	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Darmrohr AUT 4061961G1SDR0001L6	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Darmrohr Asid Bonz 4061961G1DR000046Q	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Darmrohr Pädiatrie 4061961G1DR000066U	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Darmrohr Megro 4061961G1DR000056S	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Rektalsonde 4061961G1SRS0001S7	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Urodynamik Katheter 4061961G1SCK0001HC	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Verbindungsschauch für Urodynamischen Messkatheter 4061961G1SCK0002HE	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Cystoskopie-Set 4061961G1SCS0001L4	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Biopsie-Zubehör 4061961K1SBZ0001QY	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Schläuche und Schlauchabschnitte, steril 4061961K1SSA0001PA	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Schläuche und Schlauchabschnitte, steril, Mediland 4061961K1SSA0003PE	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Komponenten für Medizinprodukte steril 4061961K1SK00001EJ	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Komponenten für Medizinprodukte steril, Teleflex 4061961K1SK00002EL	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Infusionsleitungen 4061961K2AIL0001E2	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagebeutel mit Ablass 4061961K1SDB0001HJ	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagebeutel ohne Ablass 4061961K1SDB0002HL	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Urinbeutel 4061961K1SUB0001QF	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Zubehör Redon Verbindungsschlauch 4061961K1SRZB0001F6	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainageflaschen mit Verbindungsschlauch 4061961K1SRZB0002F8	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainageflaschen steril 4061961K1SRZB0003FA	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Urinbeutel Mediland **4061961K1SUB0002QH**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Urinbeutel Zubehör Mediland **4061961K1SSK0003SU**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Schleimsauger **4061961P1SSLS001679S**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Schleimsauger Teleflex **4061961P1SSLS00269**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Nabelschnurklemme **4061961P1SNSK0014T**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Drainagen Zubehör Fixierset **4061961R2ADK0009H7**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Frauenkatheter hydrophil **4061961U1SFK0001UM**	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Frauenkatheter AUT **4061961U1SFK0005UV**	1189DE415210525A CE0482	☒ N/A or	☐ 31 December 2027		

		☐ Identification of the corresponding substitute device under MDR	☒ 31 December 2028		
Frauenkatheter 4061961U1SFK0002UP	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Frauenkatheter Euromedis 4061961U1SFK0006UX	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Frauenkatheter Asid Bonz 4061961U1SFK0003UR	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Frauenkatheter Megro 4061961U1SFK0004UT	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Tiemannspitze 4061961U1STK00012E	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Tiemannspitze Euromedis 4061961U1STK00072S	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Olivspitze 4061961U1STK00032J	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the	☐ 31 December 2027 ☒ 31 December 2028		

		corresponding substitute device under MDR			
Blasenkatheter mit Tiemannspitze Asid Bonz 4061961U1STK00042L	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Tiemannspitze Megro 4061961U1STK00052N	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Tiemannspitze Mediland 4061961U1STK00062Q	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Nelatonspitze 4061961U1SNK0001XV	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Nelatonspitze Euromedis 4061961U1SNK0007Y9	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Nelatonspitze Mediland 4061961U1SNK0006Y7	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Nelatonspitze Megro 4061961U1SNK0005Y5	1189DE415210525A CE0482	☒ N/A or ☐ Identification of the corresponding substitute	☐ 31 December 2027 ☒ 31 December 2028		

		device under MDR			
Blasenkatheter mit Nelatonspitze Asid Bonz 4061961U1SNK0004Y3	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Blasenkatheter mit Nelatonspitze hydrophil 4061961U1SNK0003XZ	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Pusher Ureterkatheter steril 4061961U1SUK00012T	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		
Komponenten für Medizinprodukte steril AUT 4061961K1SK00003EN	**1189DE415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028		

Appendix 2 – Traceability table - identification number of the OUTGOING NB to the number of the INCOMING NB

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is six (6) months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified
	2412 ☐ Not yet available	☐ Not explicitly specified

[Sample for information only – Not to be used for initial agreement]

Appendix 3 – Addendum form to specify or amend Appendices 1 and 2

ADDENDUM No. <x> to the TRANSFER AGREEMENT coming into force on <date>

between

[Manufacturer]
[Address] (in the following "CERTIFICATION HOLDER"),

[Name of outgoing Notified Body]
[Address] (in the following "OUTGOING NB")

[Name of future Notified Body]
[Address] (in the following "INCOMING NB")

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 2 (2) and/or § 8 (2):

1. The table in Appendix 1 (Legacy devices subject to transfer of appropriate surveillance) is replaced with the following table:

MDD Device name or REF	MDD Certificate Reference(s) of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Device 1	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		
Device 2	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		

2. **The table in Appendix 2 (Transition provisions) is replaced with the following table:**

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is [Months] months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Legally Binding Signature CERTIFICATION HOLDER	Legally Binding Signature INCOMING NB:	Legally Binding Signature OUTGOING NB:
[place, date]	**[place, date]**	**[place, date]**
[name] **[position]**	**[name]** **[position]**	**[name]** **[position]**