EC CERTIFICATE
Production Quality Assurance

Certificate No.:	Project No.:	Valid Until
10000370555-PA-NA-DNK	PRJN-188661-2020-PA-DNK	26 May 2024

This is to certify that the quality system of:

ArcRoyal
Virginia Road, Kells, Co. Meath, Ireland

For production and final product inspection/testing of:

Pressure lines (pressure monitoring), High Pressure Lines, Coronary Introducer Needles and sterile single use light handle cover, angiography Device, manifolds, control syringes, inflation device, infusion/administration sets, surgical skin markers, and electrosurgical tip cleaner.

Sterilization of system and procedure packs according to article 12, section 3.

Has been assessed with respect to:

The conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 July 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Hazem Tinawi
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-027 to DNV Product Assurance AS (NB 2460)	25 May 2021
1.0	To include missing part of scope	12 July 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Pressure Monitoring Lines	Pressure Monitoring Line, Male/Female, 15 cm; Pressure Monitoring Line, Male/Female, 30 cm; Pressure Monitoring Line, Male/Female, 90 cm; Pressure Monitoring Line, Male/Female, 120 cm; Pressure Monitoring Line, Male/Female, 150 cm	IIa
High Pressure Lines	Injector Line 1200 psi 75 cm Luer Lock; Injector Line 1200 psi 120 cm Luer Lock; Injector Line 1200 psi 25 cm Rotating Adaptor; Injector Line 1200 psi 75 cm Rotating Adaptor; Injector Line 1200 psi 120 cm Rotating Adaptor; Injector Line 1200 psi 50 cm Rotating Adaptor; Braided High Pressure Line, fixed, female with wing 10”; Braided High Pressure Line, fixed, female with wing 30”; Braided High Pressure Line, fixed, female with wing 48”; Braided High Pressure Line, fixed, female, rotating adaptor, 20”; Braided High Pressure Line, fixed, female, rotating adaptor, 30”; Braided High Pressure Line, fixed, female, rotating adaptor, 48”	IIa
Coronary Introducer Needle	Coronary Guidewire Introducer Needle 19ga x 38 mm, Coronary Guidewire Introducer Needle 21ga x 38 mm, Coronary Guidewire Introducer Needle 18ga x 77 mm, Coronary Guidewire Introducer Needle 18ga x 70 mm	IIa
Angiography Device	PTCA Accessory Kit; Y-Connector, single; Y-Connector, double; Torque device	Is

Manifolds	Manifold 2-port 250 psi RH RA ON, Manifold 2-port 250 psi RH RA OFF, Manifold 3-port 250 psi RH RA OFF	Is
Control Syringe	Control Syringe 10 mL, Male, Luer Lock with thumb & finger rings; Control Syringe 10 mL, Male, Rotating Adaptor with thumb & finger rings	Is
Infusion/ Admininstration Set	Admin Set AAA	Is
Inflation Device	Inflation device	Is
Light Handle cover	Light Handle Cover 1/pkt S; Light Handle Cover 2/pkt S	Is
Surgical Skin Markers	Skin Marker Std Tip, Skin Marker Fine Tip	Is
Electrosurgical tip cleaner	Cautery Tip Cleaner	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
ArcRoyal	Virginia Road, Kells, Co. Meath, Ireland

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ArcRoyal
Manufacturer address and contact details	Virginia Road, Kells, Co. Meath
Single Registration Number (SRN) (if available)	IE-MF-000004441

Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  - ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☐ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

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- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: ArcRoyal

Location & Date: Virginia Road, Kells, Co. Meath, Ireland

Signature, Print Name, Title: S Lynch, Stephanie Lynch, ArcRoyal Regulatory Affairs Specialist

Contact Details (at least email): GM-ARCROYAL-PRRC@owens-minor.com

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
12-004948 Manifold 2-port 250 psi RH RA ON	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-004951 Manifold 2-port 250 psi RH RA OFF	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-004952 Manifold 3-port	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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250 psi RH RA OFF						
12-000249 Control Syringe 10 mL, Male, Luer Lock with thumb & finger rings	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000304 Control Syringe 10 mL, Male, Rotating Adaptor with thumb & finger rings	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000210 Pressure Monitoring Line, Male/Female, 150 cm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000235 Pressure Monitoring Line,	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

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Male/Female, 15 cm						
12-000236 Pressure Monitoring Line, Male/Female, 120 cm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000237 Injector Line 1200 psi 75 cm Luer Lock	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000608 Injector Line 1200 psi 120 cm Luer Lock	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000813 Injector Line 1200 psi 25 cm Rotating Adaptor	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-000836 Pressure Monitoring Line,	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

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Male/Female, 30 cm						
12-001733 Injector Line 1200 psi 75 cm Rotating Adaptor	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001734 Injector Line 1200 psi 120 cm Rotating Adaptor	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001736 Braided High Pressure Line, fixed, female, rotating adaptor, 48"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001737 Braided High Pressure Line, fixed, female, rotating adaptor, 30"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

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12-001738 Braided High Pressure Line, fixed, female, rotating adaptor, 20"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001740 Braided High Pressure Line, fixed, female with wing 48"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001741 Braided High Pressure Line, fixed, female with wing 30"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001743 Braided High Pressure Line, fixed, female with wing 10"	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

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12-001771 Injector Line 1200 psi 50 cm Rotating Adaptor	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001776 Pressure Monitoring Line, Male/Female, 90 cm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001915 PTCA Accessory Kit	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001855 Y-Connector, single	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001856 Y-Connector, double	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-001624 Torque device	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

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12-003846 Admin Set AAA	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-004925 Coronary Guidewire Introducer Needle 19ga x 38 mm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-004924 Coronary Guidewire Introducer Needle 21ga x 38 mm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
12-004943 Coronary Guidewire Introducer Needle 18ga x 77 mm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

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12-002069 Coronary Guidewire Introducer Needle 18 ga x 70 mm	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
AR-LHCB01 Light Handle Cover 1/pkt S	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
AR-LHCB02 Light Handle Cover 2/pkt S	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
AR-26001 Skin Marker Std Tip	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
AR-26002 Skin Marker Fine Tip	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A
AR-32200 Cautery Tip Cleaner	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

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12-003704 Inflation device	10000370555-PA-NA-DNK	26 May 2024	DNV Product Assurance AS and 2460	DNV Product Assurance AS and 2460	31 Dec 2028	N/A

Directors: E. O'Dwyer, P. Deschamps | ***Secretary:*** G Rea | **Registered Office:** Virginia Road, Kells, Co. Meath, A82 R862, Ireland | **Company Registration Number:** 138763

Notified Body Confirmation Letter Reference: C682785

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework 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

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ArcRoyal
Virginia Road
Kells, Co. Meath
A82 R862
Ireland

SRN Number: IE-MF-000004441

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 03.05.2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
12-004948 Manifold 2-port 250 psi RH RA ON / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004951 Manifold 2-port 250 psi RH RA OFF / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004952 Manifold 3-port 250 psi RH RA OFF / 539153604DC34672UY	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000249 Control Syringe 10 mL, Male, Luer Lock with thumb & finger rings / 539153604DC34671UW	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000304 Control Syringe 10 mL, Male, Rotating Adaptor with thumb & finger rings / 539153604DC34671UW	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000210 Pressure Monitoring Line, Male/Female, 150 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000235 Pressure Monitoring Line, Male/Female, 15 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000236 Pressure	Class IIa	N/A	10000370555-PA-NA-

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Monitoring Line, Male/Female, 120 cm / 5369153604DC34669VB			DNK DNV Product Assurance AS and 2460
12-000836 Pressure Monitoring Line, Male/Female, 30 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001776 Pressure Monitoring Line, Male/Female, 90 cm / 5369153604DC34669VB	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000237 Injector Line 1200 psi 75 cm Luer Lock / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000608 Injector Line 1200 psi 120 cm Luer Lock / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-000813 Injector Line 1200 psi 25 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001733 Injector Line 1200 psi 75 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001734 Injector Line 1200 psi 120 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001736 Braided High Pressure Line, fixed, female, rotating adaptor, 48” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001737 Braided High Pressure Line, fixed, female, rotating adaptor, 30” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001738 Braided High Pressure Line, fixed, female, rotating adaptor, 20” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001740 Braided High Pressure Line, fixed, female with wing 48” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001741 Braided High Pressure Line, fixed, female with wing 30” / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
12-001743 Braided High Pressure Line, fixed, female with wing 10" / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001771 Injector Line 1200 psi 50 cm Rotating Adaptor / 5369153604DC34670UU	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001915 PTCA Accessory Kit / 539153604DC34692V6	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001855 Y-Connector, single / 539153604DC34690V2	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001856 Y-Connector, double / 539153604DC34690V2	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-001624 Torque device / 539153604DC34691V4	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-003846 Admin Set AAA / 539153604DC34693V8	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004925 Coronary Guidewire Introducer Needle 19ga x 38 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004924 Coronary Guidewire Introducer Needle 21ga x 38 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-004943 Coronary Guidewire Introducer Needle 18ga x 77 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-002069 Coronary Guidewire Introducer Needle 18 ga x 70 mm / 539153604DC33294UF	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-LHCB01 Light Handle Cover 1/pkt S / 539153604DC34688VF	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-LHCB02 Light Handle Cover 2/pkt S / 539153604DC34688VF	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-26001 Skin Marker Std	Class IIa	N/A	10000370555-PA-NA-

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tip / 539153604DC34684V7			DNK DNV Product Assurance AS and 2460
AR-26002 Skin Marker Fine Tip / 539153604DC34684V7	Class IIa	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
AR-32200 Cautery Tip Cleaner / 539153604DC34687VD	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
12-003704 Inflation device / 539153604DC34683V5	Class Is	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460
Procedure Packs	N/A	N/A	10000370555-PA-NA-DNK DNV Product Assurance AS and 2460 (*Procedure packs according to article 12, section 3)

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/25	C682785	Initial issue
2024/05/03	C682785	Addition of procedure packs

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.

- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.