eurofins | Expert Services

FINAS
Finnish Accreditation Service
S017 (EN ISO/IEC 17065)

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer:	Promecon GmbH Kreuslerstrasse 10, 20095 Hamburg Germany
Coverage of Certificate:	Manufacture and final inspection
Product category:	Sterile single use ultrasound probe covers and sterilization of ultrasound probe cover sets
Valid until:	27th May 2024

The manufacturer´s quality system for the manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex V Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex V in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 11th May 2021

EUROFINS EXPERT SERVICES OY

Aliisa Siljander

Sippy Kaur

Certificate no.
C-01-1180-770-21

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1180-770-21

Manufacturer:	Promecon GmbH Kreuslerstrasse 10, 20095 Hamburg Germany
Activity and product category:	Manufacture and final inspection of ultrasound probe covers. Sterilization of ultrasound probe cover sets. GMDN-code: 44713
Products:	The certificate covers the following products: *Name* — *Brand name* — *Class* Ultrasound probe covers — SonoGuard — Is Ultrasound probe covers — SonoGuard Plus — Is Sterilization of ultrasound probe cover sets (article 12) • SonoGuard set • SonoGuard Plus set
Date:	Valid from: 11th May 2021 Aliisa Siljander Sippy Kaur

EUROFINS EXPERT SERVICES OY

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

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PROMECON

Promecon GmbH, Kreuslerstr. 10, DE-20095 Hamburg

Contact Levante Röhrs
Phone +49 (40) 3690 1693
Mail roehrs@promecon-medical.de

Hamburg, 25 January 2024

Manufacturer's Declaration

Dear valued Customer,

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 certificate issued under Council Directive 93/42/EEC on Medical Devices (MDD)

  Certificate no. C-01-1180-770-21
- 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	Promecon GmbH
Manufacturer address and contact details	Kreuslerstraße 10 20095 Hamburg Germany Tel.: +49 40 36 90 16 90 Mail: info@promecon-medical.de
Single Registration Number (SRN)	DE-MF-000015290

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed devices 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:

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- **Directive Certificate as listed above**
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted for the devices listed in the attached schedule and a signed written agreement in accordance with Section 4.3, second subparagraph of Annex VII MDR is expected to be in place before 26 September 2024.

- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.

- **Devices as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices 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.

Faithfully

Dr. Alexander Calavrezos, CEO

PROMECON GMBH
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GESCHÄFTSFÜHRER DR. ALEXANDER CALAVREZOS, AMTSGERICHT HAMBURG HRB 66510, UST-ID-NR. DE192178322
COMMERZBANK AG, IBAN DE27200400000619127400, BIC COBADEFFXXX
EINE GROSSHANDELSERLAUBNIS GEM. § 52 A ABS. 1 ARZNEIMITTELGESETZ LIEGT VOR,
AUSGESTELLT AM 14.01.2019 VON DER BEHÖRDE FÜR JUSTIZ UND VERBRAUCHERSCHUTZ, HAMBURG

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Schedule of Devices

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

Identification of the devices	Directive Certificate numbers to which this confirmation is made	Original expiry date as indicated on the Directive Certificates prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged	Medical Device class	End date of extended validity / transition period
SonoGuard	C-01-1180-770-21	27.05.2024	Eurofins #0537	DQS #0297	I(s)	31.12.2028
SonoGuard Plus	C-01-1180-770-21	27.05.2024	Eurofins #0537	DQS #0297	I(s)	31.12.2028
SonoGuard Set	C-01-1180-770-21	27.05.2024	Eurofins #0537	DQS #0297	I(s)	31.12.2028
SonoGuard Plus Set	C-01-1180-770-21	27.05.2024	Eurofins #0537	DQS #0297	I(s)	31.12.2028

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Promecon GmbH

Kreuslerstraße 10

20095 Hamburg

Germany

2024-01-02

Notified Body Confirmation Letter

Reference: 170772346

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 device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

Promecon GmbH

Kreuslerstraße 10

20095 Hamburg

Germany

SRN:
DE-MF-000015290

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH 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 DQS Medizinprodukte GmbH 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 90/385/EEC (AIMDD) or 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/AIMDD 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.

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)

On behalf of the Notified Body,

A. Königshoven

Alina Königshoven

Regulatory Affairs Manager

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 (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SonoGuard	Class I devices placed on the market in sterile condition	N/A	Certificate Number: C-01-1180-770-21 NB #: 0537
SonoGuard Plus	Class I devices placed on the market in sterile condition	N/A	Certificate Number: C-01-1180-770-21 NB #: 0537
SonoGuard Set	Article 22 (Sterilization of ultrasound probe cover sets)	N/A	Certificate Number: C-01-1180-770-21 NB #: 0537
SonoGuard Plus Set	Article 22 (Sterilization of ultrasound probe cover sets)	N/A	Certificate Number: C-01-1180-770-21 NB #: 0537
OptiGuard Access	Class I devices placed on the market in sterile condition	N/A	Certificate Number: 2195-MED-1819701 NB #: 2195
OptiGuard QuickChange Pro (Ring)	Class I devices placed on the market in sterile condition	N/A	Certificate Number: 2195-MED-1819701 NB #: 2195
OptiGuard QuickChange Arthro (Ring)	Class I devices placed on the market in sterile condition	N/A	Certificate Number: 2195-MED-1819701 NB #: 2195

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

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-01-02	ID	Initial issue