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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

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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

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