# Declaration

PROMECON

according to Art. 12 of Medical Device Directive 93/42 / EEC

for

## Procedure Packs

| Product Group (Articles) |
|---|
| Cover, sterile (UMDNS Code 15-571) |
| Gel ultrasound probe, sterile (UMDNS Code 15-321) |

The product groups listed in the table contain individual procedure sets that represent treatment units in terms of Art. 12 of Council Directive 93/42 / EEC on medical devices.

The procedure packs were assembled from medical products that bear the CE mark. The mutual compatibility of the products was checked according to the manufacturer's instructions and the work steps were carried out according to the instructions.

The procedure packs have been properly packed and pertinent user instructions, including the relevant information from the manufacturer, have been included.

The composition of the sets was internally monitored, controlled, and documented in a suitable manner. The sterilisation was carried out according to the manufacturer's instructions.

Hamburg, 2021-11-01

Dr. Alexander Calavrezos

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# Anhang Produktliste
# Erklärung nach Art. 12, MDD

PROMECON

## Annex Device List

| | |
|---|---|
| Dok-Nr./File No.: | KE0103 |
| Produktgruppe:<br>Product group: | SonoGuard Plus Set with sterile Ultrasound Gel |
| Single Registration Number (SRN) | DE-MF-000015290 |
| GMDN | 44713 |
| Basis-UDI-DI<br>Basic-UDI-DI | 60434711004F |
| Zertifikatsnummer:<br>Certificate number: | C-01-1180-770-21 |
| Anzahl Seiten:<br>Number of Pages: | 1 |
| Revisions Datum:/<br>Date of Revision: | 01.11.2021 |

| Art.-Nr.<br>REF | Produkt<br>Device |
|---|---|
| US.20.180.025-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 25 cm |
| US.20.180.040-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 40 cm |
| US.20.180.080-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 80 cm |
| US.20.180.120-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 120 cm |
| US.20.180.160-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 160 cm |
| US.20.180.200-G | SonoGuard Plus Set with sterile Ultrasound Gel 18 x 200 cm |
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