PROMECON

Statement

according to Article 22 Regulation (EU) 2017/745 for Procedure Packs

Procedure Pack Producer	**PROMECON GmbH** Kreuslerstr. 10 20095 Hamburg, Germany
Single Registration Number (SRN)	**DE-PR-000035547**
Product Group	**Procedure Pack - Equipment Cover and Gel**
Basic UDI-DI	**426043471EQPCoversPP-GFD**
Trade Name Procedure Pack	***SonoGuard Set, SonoGuard Plus Set***
Article Number (REF)	**Article Numbers see Annex A**
Containing Medical Devices	**Ultrasound Probe Covers**, Class Is, CE 0297 **Sterile Ultrasound Gel**, Class IIa, CE 2292
Declaration of the Procedure Pack Producer:	We declare that products contained in the procedure packs are medical devices in accordance with Article 2 (1) Regulation (EU) 2017/745. They bear the CE mark and are to be used in accordance with their individual intended purpose and within their limits specified by their manufacturers. The mutual compatibility of the products was verified in accordance with the manufacturer's instructions, and the activities were carried out in accordance with those instructions. The procedure packs have been properly packaged, and relevant user information are supplied, incorporating the information to be supplied by the manufacturers of the devices that have been put together. Sterilisation is carried out in accordance with the manufacturer's instructions. The conformity assessment procedure has been conducted in accordance with the procedure set out in Annex IX of Regulation (EU) 2017/745. This procedure and the involvement of the Notified body is limited to aspects of the sterilisation process related to ensure sterility until the packaging is opened or damaged. The activity of combining the medical devices mentioned above into a procedure pack was subject to appropriate methods of internal monitoring, verification, and validation.
Notified Body (NB)	**DQS Medizinprodukte GmbH** August-Schanz-Straße 21 60433 Frankfurt am Main
Notified Body Identification Number:	**0297**
Certificate No.	**1000278340**
Valid until	**2031-03-16**

Hamburg, 17.06.2026 — Dr. Alexander Calavrezos, General Manager

Place, date — **Name, Function, Signature of Authorized Person**

Annex A: Ultrasound Probe Covers with Sterile Ultrasound Gel

Procedure Pack Name	REF	GMDN Cover	GMDN Gel	UMDNS Cover	UMDNS Gel	EMDN Cover	EMDN Gel
SonoGuard Set	SG.10.140.025-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.040-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.080-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.120-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.160-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.200-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Set	SG.10.140.250-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.025-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.040-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.080-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.120-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.160-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.200-G	44713	15321	15-571	15-321	T030199	Z11040185
SonoGuard Plus Set	SG.20.180.250-G	44713	15321	15-571	15-321	T030199	Z11040185