EU Quality Management Certificate

This is to certify that the company

PROMECON GmbH

Kreuslerstraße 10
20095 Hamburg
Germany

SRN: DE-MF-000015290 / DE-PR-000035547

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	550329 MDR2017Q
Certificate ID	1000278340
Effective date	2026-03-17
Expiry date	2031-03-16
Frankfurt am Main,	2026-03-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 8.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000015290 / DE-PR-000035547
Certificate ID: 1000278340

Device categories and variants covered by this certificate according to Article 52:

Device category:	**MDN 1214 - General non-active non-implantable devices used in health care and other nonactive non-implantable devices**
Product name:	Equipment Cover
Risk classification:	Is
Basic-UDI-DI:	426043471EQPCovers4W
Intended purpose:	Sterile covers allow the use of non-sterile devices for aseptically performed diagnostic or therapeutic procedures on the human body. Correctly applied, the covers create a sterile barrier around the device. Equally, they prevent the contamination of devices by microorganisms or body fluids transmitted from the patient. The covers are not intended for the use of the device in natural or surgical body orifices nor to prevent the device from being properly decontaminated between uses on patients.

Device categories and variants covered by this certificate according to Article 22 (3):

Device category:	**MDN 1214 - General non-active non-implantable devices used in health care and other nonactive non-implantable devices**
Product name:	procedure pack
Risk classification:	-
Basic-UDI-DI:	426043471EQPCoversPP-GFD
Intended purpose:	The procedure pack has no intended purpose of its own. The contained medical devices are used in accordance with their respective intended purposes

Examinations and tests performed:
550329_A214024MED dated 2024-04-10
550329_A216987MED_Equipment Covers dated 2025-12-10

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a