Erklärung nach Artikel 22 der Verordnung (EU) 2017/745
Declaration according to Article 22 of Regulation EU) 2017/745

Wir

We

B. Braun Melsungen AG
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34212 Melsungen
Deutschland / Germany
DE-PR-000005115

erklären in eigener Verantwortung, für die Behandlungseinheiten

Set für kombinierte Spinal- und Epidural Anästhesie
(Artikelnummern und Basic UDI-DI siehe Anlage I)

dass wir

a) die gegenseitige Vereinbarkeit der Medizin- (und sonstigen) Produkte entsprechend den Hinweisen der Hersteller geprüft und unsere Tätigkeiten entsprechend diesen Hinweisen durchgeführt haben,

b) das System oder die Behandlungseinheit verpackt und die einschlägigen Benutzerhinweise angegeben haben, unter Einbeziehung der Informationen, die vom Hersteller der zusammengestellten Medizin- (und sonstigen) Produkte bereitzustellen sind,

c) die Zusammenstellung von Medizin- (und sonstigen) Produkten zu einem System oder einer Behandlungseinheit unter Anwendung geeigneter Methoden der internen Überwachung, Überprüfung und Validierung vorgenommen haben.

d) die Sterilisation ist gemäß den Anweisungen des Herstellers erfolgt.

hereby declare in our own responsibility for the procedure packs

Set for Combined Spinal & Epidural Anesthesia
(article numbers and Basic UDI-DI see attachment I)

that we

(a) verified the mutual compatibility of the devices (and other products), in accordance with the manufacturers' instructions and have carried out our activities in accordance with those instructions;

(b) packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices (and other products) which have been put together;

(c) the activity of combining devices (and other products) as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

(d) The sterilization has been carried out in accordance with the manufacturer's instructions.

Effective

Datum der ersten Erklärung
2022-03

Gültig bis 2027-05-12
Gemäß gültigem EU Quality Management System Zertifikat G14 012974 0629

Date of first declaration
2022-03

Valid until 2027-05-12
According to valid EU Quality Management System Certificate G14 012974 0629

Anlage I / Attachment I

Basic UDI-DI *40392390000020492B* - Risk class III (included devices)
Systeme u. Behandlungseinheiten / Systems and procedure packs:

Art.-Nr. / Art. No.	Produktname / Product Name	CND/EMDN
4457439S	ProSet Espocan® Safety G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4457285	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4458524	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4458400	ProSet Espocan® G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4458987	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4476166	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4476700	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4477652	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4477785	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4458987N	ProSet Espocan® Soft Tip NRFit® G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS
4459865	ProSet Espocan® Soft Tip G27	A01030103 COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS

Document amendment information

Version	Description of the changes
1.0	First issue of Declaration acc. to MDR
2.0	Change CND/EMDN Code from A01030103 Needles and Kits – Spinal and Peridural Anaesthesia in Combination to A01030103 Combined Epidural and Spinal Anaesthesia Needles and Kits
3.0	Add new article code 4458987N
4.0	Add new article codes 4458400, 4476166, 4476700, 4477785
5.0	Add new article codes 4457439S, 4458524, 4458987, 4477652 Adaption of Validity and addition of EU Quality Management System Certificate G14 012974 0629
6.0	Add new article code 4457285

Title: Declaration according to Article 22 - 279-100cKIT-MDR Initiator: Sandra ? Staufenberg

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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