

**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
Carl-Braun-Straße 1
34212 Melsungen
Deutschland / Germany
DE-PR-000005115**erklären in eigener Verantwortung,
für die Behandlungseinheitenhereby declare in our own responsibility
for the procedure packs**Multipack zur Arzneimittelzubereitung**
(Artikelnummern und Basic UDI-DI siehe
Anlage I)**Multipack for drug admixture**
(article numbers and Basic UDI-DI see
attachment I)

dass wir

that we

- 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.

- (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
2022-12**Gültig bis 2027-05-12**
Gemäß gültigem EU Quality Management
System Zertifikat G14 012974 0629**Date of first declaration**
2022-12**Valid until 2027-05-12**
According to valid EU Quality Management
System Certificate G14 012974 0629

Anlage I / Attachment I**Basic UDI-DI 40392390000206529 - Risk class I (included devices)
Systeme u. Behandlungseinheiten / Systems and procedure packs:**

Art.-Nr. / Art. No.	Produktname / Product Name	CND/EMDN
4185251	ProSet Omnifix® Set 3 ml LS (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187230	ProSet Injekt® Set 2 ml LS (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187250	ProSet Injekt® Set 10 ml LS (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187260	ProSet Injekt® Set 20 ml LS (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187573	ProSet Injekt® Set 1 ml LS (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187595	ProSet Injekt® Set 10 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187828	ProSet Mini-Spike® Set Chemo V (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187906	ProSet Omnifix® Set 1 ml LS (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187908	ProSet Omnifix® Set 1 ml LS (1x = 50 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187909	ProSet Omnifix® Set 1 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187594	ProSet Injekt® Set 5 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4197595	ProSet Injekt® Set 10 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187596	ProSet Injekt® Set 20 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187827	ProSet Mini-Spike® Set (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187829	ProSet Mini-Spike® Set (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187840	ProSet Mini-Spike® Set Chemo V (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187850	ProSet Mini-Spike® Set Chemo (1x 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187851	ProSet Mini-Spike® 2 Set Chemo (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187855	ProSet Mini-Spike® V Set (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187860	ProSet Mini-Spike® Set Chemo Micro-Tip (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER

4187870	ProSet Mini-Spike® 2 Set (1x 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188220	ProSet Sterican® Mix Set G18 (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188230	ProSet Sterican® Mix Set G18 (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER

**Basic UDI-DI 403923900000206427 - Risk class IIa (included devices)
Systeme u. Behandlungseinheiten / Systems and procedure packs:**

Art.-Nr. / Art. No.	Produktname / Product Name	CND/EMDN
4088786	ProSet Perfusor® Set 50 ml LL (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4182545	ProSet Combi-Stopper Set LL (1x = 100 PCS)	A030499 ADMINISTRATION KITS - OTHER
4182553	ProSet Combi-Stopper Set LL (1x = 100 PCS)	A030499 ADMINISTRATION KITS - OTHER
4183207	ProSet Injekt® Set 2 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4185241	ProSet Omnifix® Set 3 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4185242	ProSet Omnifix® Set 5 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4185243	ProSet Omnifix® Set 20 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187210	ProSet Injekt® Set 10 ml LS (1x = 40 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187212	ProSet Omnifix® Set 10 ml LL (1x = 40 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187571	ProSet Injekt® Set 5 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187572	ProSet Injekt® Set 5 ml LL (1x = 20 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187884	ProSet Discifix® C 3-fach Set (1 = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187900	ProSet Omnifix® Set 3 ml LL (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187901	ProSet Omnifix® Set 5 ml LL (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187902	ProSet Omnifix® Set 10 ml LL (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187903	ProSet Perfusor® Set 50 ml LL (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4187904	ProSet Omnifix® Set 20 ml LL (1x = 5 PCS)	A030499 ADMINISTRATION KITS - OTHER

4187907	ProSet Omnifix® Set 30 ml LL (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188180	ProSet Sterican® Set G18 (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188185	ProSet Combi-Stopper Set LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188186	ProSet Combi-Stopper Set LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188190	ProSet Sterican® Set G20 (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188178	ProSet Combi-Stopper Set LL (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188179	ProSet Combi-Stopper Set LL (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188200	ProSet Sterican® Set G18 (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4188210	ProSet Combifix® Adapter Set (1x = 10 PCS)	A030499 ADMINISTRATION KITS - OTHER
4890957	ProSet Omnifix® Set 10 ml LL (1x = 25 PCS)	A030499 ADMINISTRATION KITS - OTHER

Document amendment information

Version	Description of the changes
1.0	First issue of Declaration acc. to MDR
2.0	Add new articles numbers 4182545, 4187572, 4187828, 4187903, 4188178, 4188179, 4188210, 4188220
3.0	Add new article codes 4088786, 4182553, 4183207, 4187210, 4187571, 4187827, 4187829, 4187840, 4187850, 4187851, 4187855, 4187860, 4187870, 4187884, 4188185, 4188186, 4188230
4.0	Add new article codes 4187595, 4187909

Title: Declaration according to Article 22 - 279-100hKIT-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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