

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
SRN DE-PR-000005115

erklären in eigener Verantwortung,
für die Behandlungseinheiten

hereby declare in our own responsibility
for the procedure packs

Set für Epiduralanästhesie
(Artikelnummern und Basic UDI-DI siehe
Anlage I)

Set for Epidural Anesthesia
(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.

Datum der ersten Erklärung
2021-11

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

Date of first declaration
2021-11

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

Anlage I / Attachment I

**Basic UDI-DI 40392390000204829 - Risk class III (included devices)
Systeme u. Behandlungseinheiten / Systems and procedure packs:**

Art.-Nr. / Art. No.	Produktname / Product Name	CND/EMDN
4449606	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450270	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450272N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450277	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450310	ProSet Perifix® G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450345	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450370	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450370N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450370S	ProSet Perifix® ONE Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4450469	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451113	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451114	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451115	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451116	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451123	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451200	ProSet Perifix® Soft Tip Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451235	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451405	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451416SN	ProSet Perifix® NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451565S	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

4451651	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451651N	ProSet Perifix® Soft Tip NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451652N	ProSet Perifix® Soft Tip NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4451686	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452259	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452409N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452429	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452500	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452658	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4452658N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453377	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453581	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453582	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453751	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453964	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4453697	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454409	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454410	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454410N	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454411	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454412	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454472	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454711	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454711N	ProSet Perifix® NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

4454722	ProSet Perifix® Soft Tip Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454722N	ProSet Perifix® Soft Tip NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454733	ProSet Perifix® ONE Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454733N	ProSet Perifix® ONE NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454936	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4454987	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455045	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455131	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455185	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455337	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455487	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455487N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455555	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455622	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4455886	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456351	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456483	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456602	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456750	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456750N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456840	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456858	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4456949	ProSet Perifix® Soft Tip G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457050	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

4457129	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457340	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457447	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457510	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457684	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457749	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457777	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457788	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457811	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457811N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457889	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457919	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457927	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457994	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457994N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4457995N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458012	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458012N	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458020	ProSet Perifix® Soft Tip G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458038	ProSet Perifix® Soft Tip G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458046	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4458412	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4458249	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458311	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4458311N	ProSet Perifix® NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4458490S	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4458974	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459003	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459006N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459121	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459148	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459202	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459210	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459660	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4459890	ProSet Perifix® Soft Tip Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459938	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459939	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4459962	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4470083S	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

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4470184	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4470060	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4470429N	ProSet Perifix® NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4472414	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476000	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476026	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476034	ProSet Perifix® ONE Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476123	ProSet Perifix® Soft Tip G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476263	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476274	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476344	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476395	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476441	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4476638	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476640N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476654	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476655	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4476735N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476760	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476761	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4476859S	ProSet Perifix® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476921	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476948N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4476964	ProSet Epican® Paed G25	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4477090N	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477100	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477112	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477308	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477319	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477340	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477405	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477448	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477448N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4477565	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4477641	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
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4477685N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477696	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477763	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477774	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477827	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477831	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477832	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477833	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477834	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477835N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477805	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477829	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477885	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477893	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477914	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477914N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477928	ProSet Perifix® ONE G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477928N	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477934	ProSet Perifix® Soft Tip Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

4477945	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4477979	ProSet Perifix® ONE G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4510046	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4510055	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4890020N	ProSet Perifix® ONE NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4893484	ProSet Epican® Paed G25	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
4895662	ProSet Epican® Paed G25	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850012	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850100	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850103	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850103N	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850104	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850107	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850303	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850312	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850333N	ProSet Perican® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850453	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850453N	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850466	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850548	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850576	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850579	ProSet Perifix® ONE NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850582	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850583	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

8850587	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850588	ProSet Perifix® ONE NRFit® Paed G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8850608N	ProSet Perifix® Soft Tip NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8851201	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8851801	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8852205	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8852702	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8853001N	ProSet Perifix® Soft Tip NRFit® Safety G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8853202	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8853203	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8854901	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8855301	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8856405	ProSet Perifix® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8857400	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8859307	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8864003N	ProSet Perifix® Soft Tip NRFit® G16	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8865001	ProSet Perifix® NRFit® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8870451	ProSet Perifix® Soft Tip G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
8870483	ProSet Perican® G18	A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS

Document amendment information

Version	Description of the changes
1.0	First issue of Declaration acc. to MDR
2.0	Add new article codes 4452500, 4453964, 4453697, 4454410, 4454936, 4455487, 4455622, 4458311, 4459939, 4470060, 4476638, 4477774, 4477928, 4477945
3.0	Add new article codes 4450310, 4450370, 4451115, 4451200, 4451405, 4452259, 4452429, 4452658, 4453581, 4454409, 4454987, 4455045, 4455555, 4456351, 4456602, 4456750, 4456858, 4457684, 4457788, 4457811, 4457919, 4457994, 4458249, 4458338, 4459121, 4476123, 4476859S, 4477833, 4477893, 4893484, 8859307
4.0	Add new article code 4459849
5.0	Add new article codes 4459938, 4476611, 8850583
6.0	Add new article codes 4450345, 4459202, 4470044, 4476000, 4470184, 4476263, 4476530, 4476655, 4476657, 4476760, 4476948N, 4477090, 4477502, 4477006, 4477914N, 4890020N, 8850548, 8855301 Change CND/EMDN designation from A01030102 NEEDLES AND KITS - PERIDURAL ANAESTHESIA to A01030102 EPIDURAL ANAESTHESIA NEEDLES AND KITS
7.0	Add new article codes 4451651N, 4451652N, 4454472, 4457749, 4458311N, 4458907, 4476034, 4476344, 4476581, 4476921, 4477014, 4477685, 4477685N, 4477674, 4477763, 4477827, 4477831, 4477834
8.0	Add new article codes 4457510, 4477805, 4477885, 4477914, 4510046, 4895662, 8850107
9.0	Add new article codes 4449606, 4450370N, 4456483, 4459709, 4470429N, 4476735N, 8850104, 8864003N Adaption of Validity and addition of EU Quality Management System Certificate G14 012974 0629
10.0	Add new article codes 4450370S, 4450469, 4451113, 4451114, 4451116, 4454411, 4457050, 4457340, 4457447, 4457889, 4457927, 4457994N, 4458974, 4459962, 4476656, 4476662, 4476658, 4476859N, 4477308, 4477634, 4477641, 4477100, 4477319, 4477564N, 8850576
11.0	Add new article codes 4454711N, 4454722N, 4454733N, 4477112, 4477448N, 4477832, 4477928N
12.0	Add new article codes 4453582, 4457129, 4458176S, 4476654, 8850587, 8856405, 8870451
13.0	Add new article codes 4451123, 4455131, 4455185, 4456840, 4459006N, 4472414, 4476395, 4477448, 4477565, 4477934
14.0	Add new article codes 4450270, 4455886, 4457995N, 4458012, 4458020, 4458038, 4458046, 4459210, 4459696, 4470168, 8850100, 8851801, 8852702, 8853202, 8854901 Change of product name for code numbers 4451651N, 4451652N, 4454722N from ProSet Perifix® Soft Tip NRFit® G18 in ProSet Perifix® Soft Tip NRFit® Safety G18 and for code numbers 4454711N, 4458311N from ProSet Perifix® NRFit G18 in ProSet Perifix® NRFit® Safety G18 and for code number 4454733N from ProSet Perifix® ONE NRFit® G18 in ProSet Perifix® ONE NRFit® Safety G18
15.0	Add new article codes 4457811N, 4458412, 4458490S, 4459695, 4459890, 4470083S, 4476026, 4477829, 8853203, 8850608N, 8865001

16.0	Add new article codes 4477340, 4477979, 8850453, 8853001N
17.0	Add new article codes 4459003, 4476441
18.0	Add new article codes 4452658N, 4453377, 4454410N, 4454733, 4455487N, 4476274, 4476640N, 4476964, 4477090N, 4477405, 8851201, 8870483
19.0	Add new article codes 4450272N, 4450277, 4451235, 4451416SN, 4451651, 4454686, 4453751, 4454412, 4454711, 4454722, 4455337, 4476761, 4477835N
20.0	Add new article codes 4451565S, 4452409N, 4456949, 4457777, 4458012N, 4458125, 4459148, 4459660, 4459776, 4477696, 4510055, 8850012, 8850103, 8850303, 8850312, 8850453N, 8850466, 8850579, 8850582, 8850588, 8852205, 8857400

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

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

UserName: Staufenberg, Sandra (stausade)
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