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

Wir | We

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Deutschland / Germany
DE-PR-000005115

erklären in eigener Verantwortung, für die Behandlungseinheiten

Set für spezifische oder allgemeine Anwendungen
(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 Specific or General Applications

(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
2022-04

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

Date of first declaration
2022-04

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

Anlage I / Attachment I

Basic UDI-DI *4039239000002060ZU* - Risk class IIa (included devices)
Systeme u. Behandlungseinheiten / Systems and procedure packs:

Art.-Nr. / Art. No.	Produktname / Product Name	CND/EMDN
4890516	ProSet Preparation Kit RA/CVC Safety	V0599 CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
4897057	ProSet Preparation Kit RA/CVC Safety	V0599 CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
4899868	ProSet Preparation Kit RA/CVC	V0599 CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER

Document amendment information

Version	Description of the changes
1.0	First issue of Declaration acc. to MDR
2.0	Add new article code 4897057 Adaption of Validity and addition of EU Quality Management System Certificate G14 012974 0629
3.0	Add new article code 4890516

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