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EUROPEAN MEDICAL DEVICE REGULATION

Statement

As Procedure Pack Producer, we

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare that

the following procedure pack

Name of system(s) / procedure pack(s) [1)]	3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad Device + I.V. Port Dressing
Reference	1665R
Basic UDI-DI	06082238401010000000014A5

containing the following products

Product Name	Reference	Basic UDI-DI	Rules of Annex VIII	Class
Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad Device	1664R	06082238401010000000039AM	Rules 4 and 14	Class III

and

Product Name	Reference	Basic UDI-DI	Rule of Annex V(MDD)	Class
Tegaderm™ I.V. Port Dressing	1668	TBD	Rule 4	Class IIa

is classified according to Article 22 p.1 of the Medical Device Regulation (EU) 2017/745 as a procedure pack.

and that

- all medical-devices included in the above system/procedure pack are CE marked;
- the mutual compatibility of the medical devices in accordance with the manufacturer's instructions (in specific regarding the products' intended purpose

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and specified limits of use) has been verified and the activities related to combining them have been carried out in accordance with those instructions;
- 3M Company packages the procedure pack;
- relevant information is supplied to users incorporating information to be supplied by the manufacturers of the medical devices which have been put together;
- the activity of combining medical devices as a procedure pack is subject to appropriate methods of internal monitoring, verification, and validation.
- sterilisation has been carried out in accordance with the manufacturer's instructions for each component.

DocuSigned by:
Nadia Battah
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8/16/2023

Nadia Battah
Regulatory Affairs Manager
3M Company, Medical Solutions Division

Date