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 packs

Name of procedure pack(s)	3M™ PICC/CVC Securement Device + Tegaderm™ I.V. Advanced Securement Dressing
Reference	1837-2100, 1839-2100
Basic UDI-DI	06082238401010000000188B7

containing the following products

Product Name	Reference	Basic UDI-DI	Rule of Annex VIII	Class
3M™ PICC/CVC Securement Device	2100	06082238401010000000209AN (not sold separately)	Rule 1	Is, MDR Council REGULATION (EU) 2017/745
Tegaderm™ I.V. Advanced Securement Dressing	1837 or 1839	06082232761010000000056D6 (not sold separately)	Rule 4	IIa, non-sterile, MDR Council REGULATION (EU) 2017/745

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

and that

- all medical-devices included in the above procedure packs are CE marked;
- the mutual compatibility of the medical devices in accordance with the manufacturer's instructions (in specific regarding the products' intended purpose 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 packs;
- 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:
Brendan Casey
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1/2/2024

Brendan Casey, Ph.D.
Regulatory Affairs Director
3M Medical Solutions Division

Date