# *EUROPEAN MEDICAL DEVICE REGULATION*

## Statement

As System or 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™ PICC/CVC Securement Device + Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing |
| Reference | 1877R-2100, 1879R-2100 |
| Basic UDI-DI | 06082238401010000000013A3 |

containing the following products

| Product Name | Reference | Basic UDI-DI | Rules of Annex VIII | Class |
|---|---|---|---|---|
| 3M™ PICC/CVC Securement Device | 2100 | NA – product not sold separately. | Rule 1 | Class Is |
| Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing | 1877R, 1879R | 06082238401010000000129Z | Rule 14 | Class III |

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

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 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 system or 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 system or 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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8/14/2023

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

Date