

	Statement per <i>Article 22</i> EU Medical Device Regulation	Page 1 of 2 Name: REG-MDR-ART22-US-05-780837 Revision: 3 State: Release
Title: MDR Article 22 Statement - 3M Tegaderm CHG Chlorhexidine Gluconate Gel Pad + I.V. Port Dressing (1665R)		

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 + 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
3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad	1664R	06082238401010000000039AM	Rules 4 and 14	Class III
Tegaderm™ I.V. Port Dressing (3M™ Tegaderm™ I.V. Transparent Film Dressing with Adhesive-Free Window)	1668NS	06082232761010000000054D2	Rule 4	Class IIa non-sterile

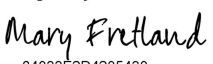
is classified according to Article 22 p.1 of the Medical Device Regulation (EU) 2017/745 as a procedure pack.

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.

Signed by:

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Mary Fretland
Senior Regulatory Affairs Manager
Medical Surgical Business

St.Paul, Minnesota 12/10/2024
Location/Date