3M Health Care Business

3M Center 2510 Conway Ave, Bldg. 275-5W-06 St. Paul, MN 55144 U.S.A. 651 733 1110



**Declaration of Conformity** 

As Legal Manufacturer We, 3M Company, 3M Health Care, 3M Center, 2510 Conway Ave, Bldg. 275-5W-06 Saint Paul, MN 55144 USA hereby declare under our sole responsibility that the CE marked products to which this declaration relates,

Tegaderm<sup>™</sup> HP Transparent Film Dressing Product numbers: 9519HP, 9525HP, 9534HP, 9536HP, 9543HP, 9545HP, 9546HP, 9548HP

are classified, according to the rule of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC as Class IIa

and

are in accordance with Annex V of Directive 93/42/EEC, as amended per 2007/47/EC on the approximation of the laws of the Member States concerning medical devices.

In addition, we declare that the above mentioned devices fulfil the applicable provisions of the Directive 93/42/EEC, as amended per 2007/47/EC.

This declaration is made on the basis of the quality assurance certificate CE 00493 delivered by BSI, 2797

> EU Representative Address 3M Deutschland GmbH Health Care Business Carl-Schurz-Str. 1 41453 Neuss, Germany

Signature:

Dianne Gibbs

Date: 28 October 2019

3M Health Care Division Regulatory Affairs Manager Medical Solutions Division

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