3M Health Care Business

2510 Conway Ave St. Paul, MN 55144 651 733 1110



Declaration of Conformity As Legal Manufacturer We, 3M Company 3M Center, 2510 Conway Ave, Bldg. 275-5W-06 St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the CE marked products to which this declaration relates,

> 3M[™] Precise[™] Staple Remover SR-1, SR-3

are classified, per rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC as Class Is devices

and

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

In addition, we declare that the above mentioned devices fulfill 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 CE00493 delivered by BSI, 2797

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

Signature:

Dianne Gibbs Regulatory Affairs Director 3M Medical Solutions Division Date: 29 April 2021

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REG-DOC-05-128706, Skin Staplers and staple removers, Version 7, Status: Review, Release Date: <<Release Date>>