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™ Vista Disposable Skin Stapler
3995-35W; 3996-15W; 3997-35R; 3998-15R

3M™ Precise™ Disposable Skin Stapler
PGX-35W; PGX-15W

3M™ Precise™ Disposable Skin Stapler
DS-5, DS-15, DS-25

are classified, per rule 6 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as Class IIa 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: _____ Date: 18 November 2019

Dianne Gibbs
Regulatory Affairs Manager
3M Medical Solutions Division

REG-DOC-05-128706, Skin Staplers and staple removers, Version 6,
Status: Release, Release Date: 11/18/2019 10:45:00 AM CST

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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 6 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.

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