3M Health Care Business

3M Center
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St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Health Care Business,
2510 Conway Ave
St. Paul, MN 55144 USA

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

3M™ Littmann® Electronic Stethoscope Models
3100, 3200, 3200T

is classified, per Rule 10 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC,
as a Class IIa active device and

is in accordance with Annex 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 CE 00493 delivered by BSI, 0086

3M Health Care Business self-declares conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and compliance to the requirements of EN 50581:2012.

For the Models 3200 and 3200T 3M Health Care Business self-declares conformity with Radio Equipment Directive 2014/53/EU of the European Parliament and of the Council of 22 May 2014 per Annex II. Applied standards and normative standards applicable to Directive 2014/53/EU are:

IEC 60601-1:2005 and C1, IEC 60601-1-6:2006 (Health & Safety)
EN 301 489-1 V1.6.1:2005, EN 301 489-17 V1.2.1:2002 (EMC)
EN 300 328 V1.7.1 (Radio)

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Signature: Dianne L. Gibbs Date: 25 July 2017

Dianne L. Gibbs
3M Health Care
Infection Prevention Division Regulatory Affairs Manager

REG-DOC-05-000025, Model 3100 and 3200 Electronic Stethoscope, Version 9,
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