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 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,

## Red Dot Resting EKG Electrode

Product numbers:

2330

are classified.

per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC as a Class I device, and

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

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.

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

Date: <u>August 19, 2014</u>

Signature:

Suzanne M. Danielson 3M Health Care

Vice President, Regulatory Affairs and Quality Assurance

Infection Prevention Division

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