3M Company

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

Declaration of Conformity

As Legal Manufacturer
We, 3M Company,
2510 Conway Ave
St. Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

Name	Product Numbers
3M Red Dot™ Monitoring Electrode with Foam Tape and Solid Gel	2238, 2255-50
3M Red Dot™ Monitoring Electrode with Foam Tape and Solid Gel	2237 and 2259-50
3M Red Dot™ Monitoring Electrode, with Micropore™ Tape and Solid Gel	2239, 2248-50 and 2249-50
3M Red Dot™ Monitoring Electrode Small Size, with Soft Cloth Tape	2245-50
3M Red Dot™ Diaphoretic Monitoring Electrode with Soft Cloth Tape and Solid Gel	2231 and 2271-50
3M™ Red Dot™ ECG Monitoring Electrode	2268-3 and 2268-5

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 Company 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

Signature: _____ Date: 19 February 2020

Dianne L. Gibbs
3M Company
Division Regulatory Affairs Manager
Medical Solutions Division

REG-DOC-05-133302, Red Dot Monitoring Electrodes, Version 9,
Status: Release, Release Date: 02/18/2020 04:39:00 PM CST
THIS DOCUMENT WAS PRINTED ON 19-Feb-2020 8:33 AM