

3M Health Care Business

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,

**3M Red Dot Electrodes**

Product numbers:

**2230, 2231, 2235, 2237, 2238, 2239, 2245, 2248, 2249, 2255, 2256, 2258, 2259, 2270, 2271**

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  
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Health Care Business  
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Signature:

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3M Health Care  
Division Regulatory Affairs Manager  
Infection Prevention Division

Date:

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