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14 October 2013

EC Declaration of conformity - Medical devices, Class IIa

We, Diversey Europe Operations B.V., hereby ensure and declare that Oxivir Plus, Oxivir+, Oxivir CE, Oxivir CE+, Oxivir CE Plus, Oxivir H Plus and Oxivir H+ with FM007720 or FM007386 used for different application methods and/or different pack sizes falling within class IIa, covered by the CE marking of conformity certificate, LRQ 4007799/B of 19 September 2013 delivered by Lloyd's Register Quality Assurance Limited, meet the provisions of Annex VII and VI of the Council Directive 93/42/EEC concerning medical devices (MDD).

Furthermore we declare that the product design and manufactured meets the applicable provisions of the MDD.

In addition we declare that the product is manufactured in conformity with the technical documentation, which is set up in accordance with section 3 of Annex VII of the MDD.

The product is designed and manufactured under the full Diversey Quality Management System based on the harmonized standard ISO 9001/2008, Quality Management System number RQA932249, certificated by Lloyd's Register Nederland B.V. and harmonised standard EN ISO 13485:2012, Quality Management System number LRQ 4007799, certificated by Lloyd's Register Quality Assurance Limited.

Sincerely,

Dr. Ir. A.B.K. Jespers

Director Global Regulatory Affairs