

EC Declaration of Conformity

European Representative: M+H VET S.R.O

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Product Name: **Cohesive bandage** **UMDNS-Code: 10288**

Classification: Class I by Rule 1 of Annex IX, MDD 93/42/EEC amended by 2007/47/EC

Conformity Assessment Route: Annex VII, MDD 93/42/EEC amended by 2007/47/EC

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directive and Standards. The products meet intended uses and all supporting documentation are retained under the premise of manufacturer and the Notified Body.

Directive:

Medical Device Directive: medical device Directive MDD (93/42/EEC)

Standards:

EN ISO 13485:2012

EN ISO 14971:2012

EN 980: 2008

EN 1041:2008

EN ISO 15223-1: 2012

EN ISO 10993-1: 2009

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN 62366:2008

93/42/EC

2007/47/EC

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