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EU-Declaration of Conformity

Mataró, 11 December 2020

We herewith declare,

Object of declaration:

Variants Omniplast tela resistente spool plasters (2559)
(Omniplast)

which was first placed on the market by Laboratorios HARTMANN S.A., meets the applicable provisions, in particular the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices, and the Real Decreto 1591/2009 for medical devices (transposition of Council Directive 93/42/EEC in Spain).

The Conformity Assessment Procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

This EU-Declaration of Conformity (version 1) is issued under the sole responsibility of Laboratorios HARTMANN S.A.

The product has been identified as a medical device in risk class I according to Rule 4 indent 1st in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 84105582559QZ
Register of responsible company for medical devices (AEMPS): RPS/89/2012

Laboratorios HARTMANN S.A.

Laboratorios HARTMANN, S.A. - MATARÓ -

Jordi Guinovart
Managing Director

Pilar Molina
Qualified Person

This EC-Declaration of conformity is performed acc. to CP-S2.2-01 Annex 39, version 3.

Registro Mercantil de Barcelona
Tomo 294, Folio 28, Hoja 18781 - Insc. 1ª de Sociedades
NIF A-08-032401