

## Consolidated EU Declaration of Conformity for Medical Devices Class IIa

Mataró, 17<sup>th</sup> June 2022

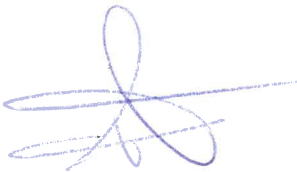
We herewith declare under our sole responsibility that the class IIa medical devices listed below, first placed on the market by Laboratorios HARTMANN S.A., Single Registration Number of Manufacturer (SRN) ES-MF-000002991, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (6) and Annex IX have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123.  
Certificate No.: G10 033979 0013.

This Consolidated EU Declaration of Conformity (version 2) is issued under the sole responsibility of Laboratorios HARTMANN S.A.

Laboratorios HARTMANN S.A.



Jordi Guinovart  
Managing Director



Pilar Molina  
Qualified Person

Valid until: 2027 - 05 - 04

This Consolidated EU Declaration of Conformity is performed acc. to C02-04-01\_Form 17, version 1.



Class IIa medical devices in conjunction with the EU Quality Management System Certificate (MDR)  
 No. G10 033979 0013

<b>Device Group (acc. to EMDN)</b>	M040403 Hydrocolloid dressings			
<b>Intended Purpose</b>	Single-use, non-active, non-implantable devices for wound and skin care			
<b>Product Name</b>	<b>Product Group Number</b>	<b>Classification Rule (according to Annex VIII of Regulation EU 2017/745)</b>	<b>Basic UDI-DI</b>	<b>Notification of placement on the market (AEMPS)</b>
Tiritas EFFECT blisters plasters	3182	4 (3 <sup>rd</sup> )	84105583182QF	PS/2016/2492
Tiritas EFFECT Hydro to cut plasters	3185	4 (3 <sup>rd</sup> )	84105583185QM	PS/2022/3739
Tiritas EFFECT Cold sores patches	3183	4 (3 <sup>rd</sup> )	84105583183QH	PS/2016/2494
Tiritas EFFECT Corns plasters	3184	4 (3 <sup>rd</sup> )	84105583184QK	PS/2016/2493

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