

Consolidated EU Declaration of Conformity for Medical Devices Class I

Mataró, 9th November 2023

We herewith declare under our sole responsibility that the class I 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 procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

This Consolidated EU-Declaration of Conformity (version 5) 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: 10th November 2025

This Consolidated EU Declaration of Conformity is performed acc. to C02-04-01_Form 17, version 2.

Device Group (acc. to EMDN)	M040101 Adhesive dressings, with absorbent pad			
Intended Purpose	Non-active, non-implantable devices for wound and skin care			
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation EU 2017/745)	Basic UDI-DI	Register of responsible company for MD (AEMPS)
Tiritas Classic	1515	4 (1 st)	84105581515Q6	RPS/100/2012
Tiritas Flexible	1516	4 (1 st)	84105581516Q8	RPS/1821/2020
Tiritas Soft	1433	4 (1 st)	84105581433Q3	RPS/99/2012
Tiritas Plastic Elastic	1514	4 (1 st)	84105581514Q4	RPS/1199/2015
Tiritas Protect plus	1517	4 (1 st)	84105581517QA	RPS/1824/2020
Tiritas Aqua	1518	4 (1 st)	84105581518QC	RPS/1196/2015
Tiritas Plastic	1519 1434	4 (1 st)	84105581519QE 84105581434Q5	RPS/80/2012
Tiritas Transparent	1521	4 (1 st)	84105581521PZ	RPS/1197/2015
Tiritas Detectables	3553	4 (1 st)	84105583553QU	RPS/97/2012
Tiritas Kids	1525	4 (1 st)	84105581525Q9	RPS/102/2012
Tiritas You have the Power	1525	4 (1 st)	84105581525Q9	RPS/1822/2020
Tiritas PJMasks	1525	4 (1 st)	84105581525Q9	RPS/1823/2020
Tiritas Mr. Wonderful	1525	4 (1 st)	84105581525Q9	RPS/1661/2021
Tiritas Bluey	1525	4 (1 st)	84105581525Q9	RPS/2755/2023
Tiritas Soft Silicone	2907	4 (1 st)	84105582907R2	RPS/1672/2020

Device Group (acc. to EMDN)	M040499 Dressings for wounds, sores and ulcerations – others.			
Intended Purpose	Non-active, non-implantable devices for wound and skin care.			
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation EU 2017/745)	Basic UDI-DI	Register of responsible company for MD (AEMPS)
Tiritas pies	2521	4 (1 st)	84105582521Q8	RPS/30/2016

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Device Group (acc. to EMDN)	M050101 Plasters on spools (rolls).			
Intended Purpose	Non-active, non-implantable devices for wound and skin care.			
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation EU 2017/745)	Basic UDI-DI	Register of responsible company for MD (AEMPS)
Omniplast	2559	1	84105582559QZ	RPS/89/2012
Esparadrapo tela	1685	1	84105581685QY	RPS/89/2012
Omnipor	1692	1	84105581692QV	RPS/90/2012
Esparadrapo papel	1692	1	84105581692QV	RPS/90/2012
Omnipor skin color	1692	1	84105581692QV	RPS/82/2018

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