

Consolidated EU-Declaration of Conformity for Medical Devices Class I

Mataró, 14th July 2021

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. (ES-MF-000002991), comply with 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.

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 2) is issued under the sole responsibility of Laboratorios HARTMANN S.A.

Laboratorios HARTMANN S.A.



Jordi Guinovart
Managing Director



Pilar Molina
Qualified Person

This EC-Declaration of conformity is performed acc. to CP-S2.2-01 Annex 44, version 1.

| 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/1672/2020 |
| 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/1821/2020 |
| Tiritas PJMasks | 1525 | 4 (1 st) | 84105581525Q9 | RPS/1823/2020 |
| Tiritas Mr. Wonderful | 1525 | 4 (1 st) | 84105581525Q9 | RPS/1661/2021 |
| Tiritas Soft Silicone | 2907 | 4 (1 st) | 84105582907R2 | RPS/1672/2020 |
| Tiritas pies | 2521 | 4 (1 st) | 84105582521Q8 | RPS/30/2016 RPS/31/2016 RPS/32/2016 RPS/33/2016 |
| Omniplast | 2559 | 1 | 84105582559QZ | RPS/89/2012 |
| Esparadrapo tela | 1685 | 1 | 84105581685QY | RPS/89/2012 |
| Omnipor | 1692 | 1 | 84105581692QV | RPS/90/2012 |
| Omnipor skin color | 1692 | 1 | 84105581692QV | RPS/82/2018 |
| Esparadrapo papel | 1692 | 1 | 84105581692QV | RPS/90/2012 |

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