EC Declaration of Conformity



DIRECTIVE 93/42/EEC AMENDED BY DIRECTIVE 2007/47/EC / DECREE-LAW 145/2009 OF 17 JUNE

Albino Dias de Andrade, S.A.

Rotunda do Complexo Desportivo, 15 4595-069 Seroa Paços de Ferreira Portugal

SRN: PT-MF-000002823

Declares that the medical devices described hereafter: Sterile crepe bandages, brand ADA Bandages, itemised on pages 2

Have been classified as Class I-Sterile DM (Annex IX, rule 4) and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, and are in conformity with the harmonized standards EN 14079:2003, EN ISO 13485: 2016, EN ISO 14971:2012, EN ISO 11737-1:2006, EN ISO 11607-1:2009, EN ISO 17665-1:2006 and EN ISO 15223-1:2016, and the Ph Eur monograph/s for sterility and are subject to the procedure set out in Annex II (excluding section 4) of the Directive 93/42/EEC, as amended by Directive 2007/47/CE, under the supervision of the Notified Body number 1639, the SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerp, Belgium, as stated in the EC certificate number ES 19/86854.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Paços de Ferreira, 12/06/2023

С€ 1639

Joana Campelos Technical Director

On behalf of Albino Dias de Andrade, S.A.

ALBINO DIAS DE ANDRADE, S.A.

Mod.123.DQ.0 1

Edition 1 Date:20/04/2021

Page 1 of 2

EC Declaration of Conformity



DIRECTIVE 93/42/EEC AMENDED BY DIRECTIVE 2007/47/EC / DECREE-LAW 145/2009 OF 17 JUNE

Sterile bandages, references:

| Reference | Description |
|----------------|----------------------------------------------------------|
| 14105010405012 | Crepe bandage 4mx5cm 105gr Sterile/CT/DP |
| 14105010405019 | Crepe bandage 4mx5cm 105 gr, Sterile DP/CT cardboard box |
| 14105010407012 | Crepe bandage 4mx7cm 105gr Sterile/CT/DP |
| 14105010407019 | Crepe bandage 4mx7cm 105 gr, Sterile DP/CT cardboard box |
| 14105010410012 | Crepe bandage 4mx10cm 105gr Sterile/CT/DP |
| 14105010415012 | Crepe bandage 4mx15cm 105gr Sterile/CT/DP |
| 14105010420012 | Crepe bandage 4mx20cm 105gr Sterile/CT/DP |
| 14105011010012 | Crepe bandage 10mx10cm 105gr Sterile/CT/DP |
| 14105011015012 | Crepe bandage 10mx15cm 105gr Sterile/CT/DP |
| 14105010405001 | Crepe bandage 5cm 105gr Sterile |
| 14105010407001 | Crepe bandage 7cm 105gr Sterile |
| 14105010410001 | Crepe bandage 10cm 105gr Sterile |
| 14105010415001 | Crepe bandage 15cm 105gr Sterile |
| 14105010420001 | Crepe bandage 20cm 105gr Sterile |
| 80105010405019 | Crepe bandage 4mx5cm 105 gr, sterile DP/CT |
| 80105010407019 | Crepe bandage 4mx7cm 105 gr, sterile DP/CT |