

## EU DECLARATION OF CONFORMITY

### THE MANUFACTURER: LABORATORIOS HERBITAS, S.L.

Head Office: C/ Periodista Badía 13B 46134. Foios. Valencia. (Spain)	Production Plant: C/ Caiguda, Parcela 21, Pol.Ind. Les Eres 46180. Benaguasil. Valencia. (Spain)
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We hereby declare under our sole responsibility that the products detailed in annex I meet the requirements of the Regulation (EU) 2017/ 745 of the European Parliament and of the Council of 5<sup>th</sup> April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) N° 178 / 2002 and the Regulation (EC) N° 1223/2009 and repealing Council Directive 90/385/ECC and 93/42/EC (text with EEA relevance) as well as the following harmonized standards:

- ✓ EN 1041: 2008 Information supplied by the manufacturer of medical devices.
- ✓ EN ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- ✓ EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices.
- ✓ EN ISO 13485: 2016 + AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes.

**RISK CLASS OF DEVICE:** Medical Device Class I

**NOTIFIED BODY:** N/A

**ROUTE OF CONFORMITY ASSESSMENT:** Annex IX

**PLACE:** Valencia (Spain)

**DATE:** 25.05.2021

**SIGNATURE**



Mr. Juan Tejedor Neira  
Managing Director – Laboratorios Herbitas, S.L.

**ANEXO I / ANNEX I:**

PRODUCTO / PRODUCT	REFERENCIA / REFERENCE	UDI – DI – BASICO / BASIC
Separator – Gel Toe Separator	103_2012_L, M, S	84351355LUNAGELWA
Corectus – Gel Toe Spreader	103_2018_L, M, S	84351355CARRETEGELZQ
Medi Gel Separator – Gel Toe Spreader with a Ring	103_2002_S, L	84351355GELRINGQZ
Duosafe – Gel Toe Spreader with Two Loops	103_2017	84351355SEPARA2TY
Medicus – Gel Bunion Shield	103_2019	84351355JUANETESGEL5L
Medi Corect – Gel Toe Spreader with Bunion Shield	103_2020	84351355DUPLIGEL7U
Hallux Soft Cover – Gel Toe Spreader with Bunion Shield and Two Loops	103_2001	84351355TRIPLIGELXV
Medicus Band – Elastic Band with a Gel Insert, Protecting Bunion	103_2016	8435135512040000A6
Hallux Med Cover – Elastic Band with a Toe Spreader and with a Gel Insert Protecting Bunion	103_2000	84351355DUPLIBANDM4
Support – Gel Toe Crest with a Ring	103_2013_LL, LP, ML, MP, SL, SP	84351355RATONGEL9A
Toes Separator – Gel Toe Crest with Three Rings	103_2003_L, P	84351355AMERICANOBP
Toes Support – Plastic Foam Toe Crest with Elastic Ring	103_2009_SL, SP, ML, MP, LL, LP	84351355RATONPIELUB
Protectube – Textile-Gel toe Tube (for cutting)	103_2015_M, S	84351355RIZOUE
Protect Tube+ – Toe Tube, made of elastic textile material with gel pads (for cutting)	103_2004_S, M, L	8435135516140200CZ
Single Tube – Gel Toe Tubing	103_2006_S, L	8435135510010X00E6
Toe Cap – Gel Toe Cap	103_2007_S, M, L	84351355DEDILGELRZ
Corn Pads – Protective Self-adhesive Gel Corn Pads	103_2011	8435135522050100B9
Toe Shield – Gel Tailor’s Bunion Shield with a Loop	103_2008	84351355SASTRES4

Promed – Gel Metatarsal Cushion	103_2021	8435135514040000B8
Metatarsal Med Cover – Elastic Band with a Gel Cushion Protecting the Ball of the Foot	103_2005_S, L	84351355COMODIGELGU
Active Hallux Corectus – Textile corrective Band for a foot with Hallux Valgus for Using During the Day	103_2010	843513551275511XH5
Focus – Silicone Heel Pads	103_2014_L, M, S	84351355DUPLOQ9