



**Declaration of Conformity  
according  
EU MDR 2017/745**

Page 1 of 2

**Declaration of Conformity  
Podological cushions made of polymeric gel**

**EMDN-Code: V080399 – Medical Cushions – Other**

manufactured by:

**SUAVEPIE SAIC**

Ramón Falcón 2232 in 1406 Buenos Aires, Argentina

SRN-Code: AR-MF-000005456

**Basic UDI: PP 12284 V080399 23**

Art. N°	Professional Packs for Podologists		
Suavepie	Product name in English	Qty	UDI-DI
9-69-100	GEHWOL Bunion Cushion G	2 p	111881827314
9-69-210	GEHWOL Small Toe Cushion G	2 p	111881829667
9-69-320	GEHWOL Bunion Cushion G with Toe Separator large	4 p	111881831027
9-69-310	GEHWOL Bunion Cushion G with Toe Separator small	4 p	111881830461
9-81-120	GEHWOL Metatarsal Cushion G large	2 p	111881867572
9-81-110	GEHWOL Metatarsal Cushion G small	2 p	111881866909
9-87-130	GEHWOL Heel Cushion G with gel waves, high rim, large	2 p	111881881863
9-87-120	GEHWOL Heel Cushion G with gel waves, high rim, medium	2 p	111881880173
9-87-110	GEHWOL Heel Cushion G with gel waves, high rim, small	2 p	111881879379
9-75-120	GEHWOL Hammer Toe Cushion G large right	2 p	111881860044
9-75-120	GEHWOL Hammer Toe Cushion G large left	2 p	111881861734
9-75-110	GEHWOL Hammer Toe Cushion G small right	2 p	111881858684
9-75-110	GEHWOL Hammer Toe Cushion G small left	2 p	111881859250
9-71-311	GEHWOL Corn Protection Ring G medium	12 p	111881847443
9-71-310	GEHWOL Corn Protection Ring G small	12 p	111881844524
9-71-200	GEHWOL Correction Ring G	12 p	111881843958
9-71-140	GEHWOL Toe Protection Ring G large 36 mm	12 p	111881842268
9-71-130	GEHWOL Toe Protection Ring G medium 30 mm	12 p	111881841605
9-71-120	GEHWOL Toe Protection Ring G small 25 mm	12 p	111881839121
9-71-110	GEHWOL Toe Protection Ring G mini 18 mm	12 p	111881838555
9-71-512	GEHWOL Double Toe Protection Ring G large	6 p	111881837989
9-71-511	GEHWOL Double Toe Protection Ring G medium	6 p	111881836202
9-71-510	GEHWOL Double Toe Protection Ring G small	6 p	111881835636
9-71-411	GEHWOL Double Small Toe Protection Ring G large	6 p	111881833380
9-71-410	GEHWOL Double Small Toe Protection Ring G small	6 p	111881832717
9-73-120	GEHWOL Toe Cap G medium	6 p	111881855765



**Declaration of Conformity  
according  
EU MDR 2017/745**

Page 2 of 2

9-73-110	GEHWOL Toe Cap G small	6 p	111881854075
9-73-100	GEHWOL Toe Cap G mini	6 p	111881853412
9-76-130	GEHWOL Toe Spreader G large	4 p	111881865219
9-76-120	GEHWOL Toe Spreader G medium	4 p	111881864653
9-76-110	GEHWOL Toe Spreader G small	4 p	111881862300
9-90-130	GEHWOL Toe Separator GD large	15 p	111881884782
9-90-120	GEHWOL Toe Separator GD medium	15 p	111881883092
9-90-110	GEHWOL Toe Separator GD small	15 p	111881882429
9-72-130	GEHWOL Toe Separator G large	15 p	111881851156
9-72-110	GEHWOL Toe Separator G small	15 p	111881848009

are classified as a medical device class 1 according to MDR 2017/745 and are manufactured following the regulations of MDR 2017/745. The Essential Requirements of Annex I of MDR 2017/745 are fulfilled.

Conformity Assessment Procedure: Article 52 (7) and Annex IV of MDR 2017/745

Classification: **Class 1**, Annex VIII, Chapter III, Rule 1

EC REP/ EAR: AF Pharma Service Europe SL

ES-AR-000018076

.....Muntaner 281

08021 Barcelona, Spain

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Date 12.05.2025

Place: Buenos Aires, Argentina

  
Gustavo Labanowski – Managing Director