Declaration of Conformity

The EU Declaration of Conformity is under the sole responsibility of the manufacturer.

The device covered by this present declaration is in conformity with EU 2017/745.

Device Identification

Device name: Scholl Ball of Foot Cushion

Brand: Scholl

Reference: MDR007

Issue Number: Issue 1.0

Component Number: CU000010

Basic UDI: The basic UDI-DI for the Scholl Ball of Foot Cushion is 5000158MDR007AZ

GMDN Code: 36295

Legal Manufacturer

Name: Reckitt Benckiser Healthcare (UK) Ltd

Address: Dansom Lane, Hull, HU8 7DS

Country: United Kingdom

SRN: Competent Authority issuance of SRN currently not obtainable

Authorised Representative / Distributor in Europe

Name: RB NL Brands B.V.

Address: Schiphol Boulevard 207, 1118 BH Schiphol

Country: Netherlands

SRN: Competent Authority issuance of SRN currently not obtainable

Registration Information

This device has been classified as a Class 1 self-certification Medical Device under the Medical Device Regulation 2017/745 and therefore not subject to approval of the notified body.

Date CE marked: 05 May 2021

Date originally CE marked in accordance with Directive 93/42/EEC: 05 December 2005

Conformity Assessment

Device Classification: According to Annex VIII of the Medical Device Regulation EU 2017/745: Class I, Rule 1

Conformity Assessment Route: Medical Device Regulation EU 2017/745 - Annex IV, Declaration of Conformity

Applicable Legislative Actions: Refer to Appendix 1 of the Declaration of Conformity

Intended Use

Scholl Ball of Foot Cushion is a non-invasive device intended for short term use.

The intended use of the device is to cushion and protect the ball of the foot by providing immediate relief from burning pain or tender areas on the ball of the foot. The device works via a physical mode of action by cushioning and protecting the ball of the foot. In addition, the device helps prevent the build-up of hard skin by reducing the friction between the user's ball of foot and external surfaces.

Reckitt Benckiser Healthcare (UK) Ltd declares that the above-mentioned devices are in conformity with Annex I General Safety and Performance Requirements and the provisions of EU 2017/745 and conforms to the standards listed in Appendix 1 of the Declaration of Conformity.

Signature

Name: Samantha Neilson

Function: Global Regulatory

Signature: DocuSigned by: Samantha Neilson 5B8C7758285B449...

Date: 05-05-2021

Appendix to the Declaration of Conformity

Appendix 1: Applicable Legislative acts

Directives/Regulations

Directive/Regulation Number and Date	Directive/Regulation Name
MDR EU 2017/745	European Medical Device Regulation 2017/745

Harmonised Standards

Standard Number and Date	Standard Name
BS EN ISO 13485:2016	Medical Devices. Quality Management Systems
BS EN ISO 10993-1:2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process.
BS EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
BS EN ISO 10993-9:2019	Framework for identification and quantification of potential degradation products
BS EN ISO 10993-10:2014	Biological Evaluation of medical devices. Tests for irritation and skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity
BS EN ISO 10993-13:2010	Identification and quantification of degradation products from polymeric medical devices
BS EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances.

BS EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1:2016	Graphical symbols for use in labelling of medical devices
BS EN 62366-1:2015 – Annex C	Part 1: Application of usability engineering to medical device
BS EN ISO 3758:2012	Textiles. Care labelling code using symbols

Other Applicable Standards

Standard Number and Date	Standard Name
Not Applicable	Not Applicable

Guidance, Common Specifications, Implementing Acts & Delegated Acts

Number or Reference of Document	Name of Document	Date & Version
MEDDEV 2.7/1	Clinical Evaluation Report	June 2016, Revision 4.0

Appendix 2: Variants and Pack Sizes

Scholl Ball of Foot Cushion is sold in the following variants and Pack sizes in the EU

Formulation Code	Local Device Name	Market	Pack Size
CU000010	Scholl Druckstellen Schutz-Kissen	Germany Switzerland Austria	1 pair

Scholl Ball of Foot Cushion is sold in the following variants and Pack sizes outside of the EU.

Formulation Code	Local Device Name	Market	Pack Size
CU000010	Scholl Ball of Foot Cushion	Australia	1 pair
CU000010	Ball of Foot Cushion	Japan	1 pair

Appendix 3: Languages accepted in the EU Member States and other European Countries

Country	Official and National Languages
Austria	German, Slovene, Croatian
Belgium	Dutch, French, German
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek, Turkish, English
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish, Swedish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	Irish, English
Iceland	Icelandic
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	Luxembourgish, French, German
Malta	Maltese
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovenian
Spain	Spanish, Catalan, Galician, Basque
Sweden	Swedish

Appendix 4: Declaration of Conformity Translation

As per Article 19 of MDR (EU) 2017/745, '*Declarations shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.'*

Translated DoC's will be generated upon request.

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SIGNATURE PAGE

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Date (GMT)	Signed by	Reason
05-May-2021 09:07:35	Hussey Hannah (HHussey)	Signing as Approver