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 Medical Device Regulation EU 2017/745.

Device Identification

Device Name: Scholl Pads and Plasters

Brand: Scholl

File Reference: MDR 026

Issue Number: 1.0

Component Number:

Scholl Corn Foam Cushion – CU000013 / 8328740

Scholl Soft Corn Cushioning Pad – 4000628 / 8328833

Scholl Callus Foam Cushion – CU000011 / 8328739

Scholl Pressure Point Foam Padding – CU000008 / 8328742

Scholl Sore Spot Moleskin – CU000007 / 8328831

Basic UDI: The basic UDI-DI for Scholl Plaster and Pads is 5000158MDR026B5.

GMDN Code: 36295

Legal Manufacturer

Name: Reckitt Benckiser Health (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

Notified Body ID: Not applicable

Notified Body Address: Not applicable

CE Certificate Number: Not applicable

Date CE marked: 02 December 2020

Date originally CE marked in accordance with MDD 93/42/EEC is given in table below:

Global Variant Name	**Date of Initial CE Mark**
Scholl Corn Foam Cushion	September 1999
Scholl Soft Corn Cushioning Pad	August 2019
Scholl Callus Foam Cushion	April 2004
Scholl Pressure Point Foam Padding	November 2008
Scholl Sorespot Moleskin	April 2005

Conformity Assessment

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

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

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

Intended Use

These devices achieve their intended use via a physical mode of action. The intended use of the devices is to provide symptomatic pain and pressure / friction relief to the feet.

Reckitt Benckiser Healthcare (UK) Ltd. declares that the above-mentioned device(s) are in conformity with Annex I General Safety and Performance Requirements and the provisions of EU 2017/745 and conforms to the legislative acts detailed in Addendum 1 of the Declaration of Conformity.

Signature

Name: Mark Ainsworth

Function: Global Regulatory

Signature: DocuSigned by: Mark Ainsworth BC84284D7A8446A...

Date: 02-12-2020

Appendix to the Declaration of Conformity

Appendix 1: Applicable Legislative acts

Directives / Regulations

Directive/Regulation Number	Directive/Regulation Name
MDR EU 2017/745	European Medical Device regulation or Medical Devices Directive

Harmonised Standards

Standard Number and Date	Standard Name
BS EN ISO 13485:2016	Medical Devices. Quality Management Systems
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. Tests for *in vitro* cytotoxicity.
ISO 10993-9:2019	Biological evaluation of medical devices. Framework for identification and quantification of potential degradation products.
BS EN ISO 10993-13:2010	Biological Evaluation of medical devices. Identification and quantification of degradation products from polymeric medical devices.
BS EN 10993-17: 2009	Biological evaluation of medical devices. Establishment of allowable limits for leachable substances.
BS EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1: 2016 (partially met)	Graphical symbols for use in labelling of medical devices
BS EN 62366-1: 2015	Annex C: Application of usability engineering to medical device

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 rev 4	Clinical Evaluation Reports (CER) for Medical Devices	June 2016, Revision 4
MEDDEV 2.12/1 rev. 8	Vigilance system (2019 – Additional guidance)	July 2019, Revision 8

Appendix 2: Variants and Pack Sizes

The Scholl Pads and Plasters are sold in the following variants in the EU.

Formulation	Local Device Name	Market
8328740	Scholl Cors Feutres Protecteurs	France
CU000007	Scholl Druckstellen Pflaster - Kurotex	Austria
CU000007	Scholl Druckstellen Pflaster - Kurotex	Germany
CU000007	Scholl Druckstellen Pflaster - Kurotex	Switzerland
CU000008	Scholl Druckstellen Pflaster - extra weich	Austria
CU000008	Scholl Druckstellen Pflaster - extra weich	Germany
CU000008	Calli e Duroni Cerotto ritagliabile doppio spessore - protezione - 1 foglio	Italy
CU000008	Scholl Druckstellen Pflaster - extra weich	Switzerland
CU000008	Scholl Pressure Point Foam Padding	United Kingdom
CU000011	Duroni cerotti in lattice	Italy
CU000013	Scholl Druckschutz Schaum-Pflaster	Austria
CU000013	Scholl Likdoorn Beschermring - Ovaal - Schuim / Protecteurs de Cors - Ovale - Mousse	Belgium
CU000013	Scholl Druckschutz Schaum-Pflaster	Germany
CU000013	Scholl Corn Foam Cushions	Ireland
CU000013	Calli – Cerotti in Lattice (9 Cerotti)	Italy
CU000013	Scholl Protecteurs de Cors - Ovale - Mousse	Luxembourg
CU000013	Scholl Druckschutz Schaum-Pflaster	Switzerland
CU000013	Scholl Corn Foam Cushions	United Kingdom

The Scholl Pads and Plasters are sold in the following variants in non-EU markets.

The Scholl Soft Corn Cushioning Pad is currently sold in Japan and not yet marketed in the EU.

Formulation	Local Device Name	Market
8328833	Scholl Soft Corn Cushion	Japan
8328740	Scholl Corn Foam Cushions	Australia
8328740	Scholl Corn Foam Cushions	New Zealand
CU000008	Scholl Pressure Point Foam Padding	Australia
CU000008	Scholl Pressure Point Foam Padding	India
CU000013	Scholl Corn Foam Cushions	Brunei Darussalam
CU000013	Scholl Corn Foam Cushion	India
CU000013	Scholl Corn Foam Cushion	Singapore

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
03-Dec-2020 09:33:27	Marrs Louise (LMarrs)	Signing as Approver