

## **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 MDR 2017/745.

## **Device Identification**

Device names:

Scholl InBalance insole – Everyday Knee to Heel (S)	3076779
Scholl InBalance insole – Everyday Knee to Heel (M)	8312958
Scholl InBalance insole – Everyday Knee to Heel (L)	3076780
Scholl InBalance insole – Heel (S)	3076778
Scholl InBalance insole – Heel (M)	8312957
Scholl InBalance insole – Heel (L)	3076775
Scholl InBalance insole – Arch (S)	3076777
Scholl InBalance insole – Arch (M)	8312956
Scholl InBalance insole – Arch (L)	3076776
Scholl InBalance insole – Lower Back (S)	3076785
Scholl InBalance insole – Lower Back (M)	8312954
Scholl InBalance insole – Lower Back (L)	3076786
Scholl InBalance insole – Plantar Fasciitis (S)	3076784
Scholl InBalance insole – Plantar Fasciitis (M)	8312960
Scholl InBalance insole – Plantar Fasciitis (L)	3076783

Brand: Scholl

Reference: MDR027

Issue Number: 03

Basic UDI: The Basic UDI-DI assigned to the Scholl InBalance insole range is 50565858MDR027J8.

GMDN Code: 41575

SRN: Not obtained yet and will be addressed in the next update.

### **Legal Manufacturer**

Name: Scholl's Wellness Company

Address: 2 Arlington Square, Downshire Way, Bracknell, RG12 1WA

Country: United Kingdom

### **Authorised Representative / Distributor in Europe**

Name: Scholl's Wellness Company B.V.

Address: Luna ArenA, Herikerbergweg 238, 1101 CM Amsterdam, The Netherlands

Country: Netherlands

### **Registration Information**

Notified Body ID: Not applicable (Class I medical devices)

Notified Body Address: Not applicable (Class I medical devices)

CE Certificate No.: Not applicable (Class I medical devices)

Date CE marked:

Heel, Knee to Heel, Arch, Lower Back; 8<sup>th</sup> March 2019

Plantar Fasciitis;

### **Conformity Assessment**

Classification: Medical Device, Class I

Rule: I

Conformity Assessment Route: Annex IV

Standard Applied: Refer to Addendum 1 of the Declaration of Conformity

## Intended Use

The Scholl InBalance insoles are a range of pre-fabricated insoles which are indicated to relieve a range of foot and lower body pains. These self-select insoles are intended to be used in an adult population who experience mild intermittent musculoskeletal aches and pains, as a consequence of prolonged periods of standing or walking.

The naming of the Scholl InBalance insole range; Knee to Heel, Heel, Lower Back Arch and Plantar Fasciitis aims to drive relevance for a larger proportion of the target population.

Therefore, in summary, the intended use of each device is specifically to provide support, increase stability, reduce shock and redistribute plantar pressures in relevant areas of the foot to reduce pain in both the feet and other areas of the lower body over a total shelf life of three years, and is worn by the consumer throughout the normal working period of the day ie approximately 8 hours. The devices are not suitable for chronic, severely acute pain or pains likely attributable to a trauma or a severe gait abnormality.

For more detailed information pertaining to the indications, contra-indications, warnings and residual risks to the end user, please refer to Section 2: *'Information to be supplied by the manufacturer'*.

Scholl's Wellness Company 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 Addendum 1 of the Declaration of Conformity.

## Signature

Name and function: Jessica Bridgewater, Regulatory Manager

Signature: *Jessica Bridgewater*  
Electronically signed by: Jessica  
Bridgewater  
Reason: I approve this document.  
Date: Dec 20, 2022 08:35 GMT

Date: 20-Dec-2022

## Addendum to the Declaration of Conformity

### Appendix 1:

#### Directives/Regulations

Directive/Regulation Number and Date	Directive/Regulation Name
MDR EU 2017/745	European Medical Device regulation 2017/745
MEDDEV 2.7.1 Rev. 4 June 2016	European commission / Guidelines on Medical Devices

#### Harmonised Standards

Standard Number and Date	Standard Name
BS EN ISO 13485:2016	Medical Devices. Quality Management Systems.
BS EN ISO 15223-1: 2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
BS EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
BS EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
BS EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: 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	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products.
BS EN ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for systematic toxicity
BS EN ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for irritation and skin sensitization

BS EN ISO 10993-13:2010	Biological evaluation of medical devices — Part 13: 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 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for Irritation.
BS EN ISO 14971:2019	Application of risk management to medical devices
ISO 24971: 2020	Guidance on the application of Risk Management
BS EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 9001:2015	Quality management
IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices

## Implementing Acts

Implementing Act Number/Reference	Implementing Act	Date
Implementation decision (EU) 2019/939 ( <i>Article 27 (2) MDR</i> )	Designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of Medical Devices	6 June 2019

## Appendix 2: Variants and Pack Sizes

The Scholl InBalance Insole Range are sold in the following variants and Pack Sizes.

Formulation code	Local Tradename	Market	Pack size
3076775	SCHOLL IN BALANCE ORTHOTICS KNEE TO HEEL (M & L) / SCHOLL IN BALANCE ORTHOTICS HEEL (M & L)	Ireland	1

	IN-BALANCE CALCANHAR E TORNOZELO (L)	Portugal	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_HÄL/HÆEL/KANTAPÄÄ (L)	Sweden	1
	IN-BALANCE TOBILLO Y TALÓN (L)	Spain	1
	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆEL/KANTAPÄÄ (L)	Norway	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆEL/KANTAPÄÄ (L)	Denmark	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆEL/ KANTAPÄÄ (L)	Finland	1
	SCHOLL IN-BALANCE, HEEL INSOLE	United Kingdom	1
	SCHOLL INBALANCE INSOLE- EVERYDAY KNEE TO HEEL	United Kingdom	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	Australia	1
	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	New Zealand	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_TALLONE, TALLONITE, TENDINE D'ACHILLE	Italy	1
3076776	SCHOLL IN-BALANCE, ARCH INSOLE	United Kingdom	1

SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆEND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1
IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆEND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1
SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	New Zealand	1
BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆEND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1
IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ARCO PLANTARE, PIEDE PIATTO	Italy	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆEND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Switzerland	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Austria	1
SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	Australia	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Germany	1

3076777	SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	New Zealand	1
	SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
	IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1
	SCHOLL IN-BALANCE EINLEGESOHLEN BEI SCHMERZEN IM FUSSGEWÖLB	Austria	1
	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN- BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1
	SCHOLL IN-BALANCE, ARCH INSOLE	United Kingdom	1
	SCHOLL IN-BALANCE EINLEGESOHLEN BEI SCHMERZEN IM FUSSGEWÖLB	Germany	1
	IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
	SCHOLL IN-BALANCE EINLEGESOHLEN BEI SCHMERZEN IM FUSSGEWÖLB	Switzerland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1



	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ARCO PLANTARE, PIEDE PIATTO	Italy	1
	SCHOLL OTHORTICS BALL OF FOOT & ARCH (SMALL)	Ireland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1
3076778	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/ HÆL/ KANTAPÄÄ (S)	Finland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆL/KANTAPÄÄ (S)	Norway	1
	SCHOLL ORTHOTICS KNEE TO HEEL (S)	Ireland	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆL/KANTAPÄÄ	Denmark	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_HÄL/HÆL/KANTAPÄÄ (S)	Sweden	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_TALLONE, TALLONITE, TENDINE D'ACHILLE	Italy	1
	IN-BALANCE TOBILLO Y TALÓN (S)	Spain	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	New Zealand	1

	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL IN-BALANCE, HEEL INSOLE	United Kingdom	1
	IN-BALANCE CALCANHAR E TORNOZELO (S)	Portugal	1
3076779	SCHOLL ORTHOTICS KNEE TO HEEL (S)	Ireland	1
	SEMELLE ANTI-DOULEUR GENOU ET TALON	France	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (S)	Austria	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (S)	Switzerland	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (S)	Germany	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Sweden	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE EVERYDAY-DAL GINOCCHIO AL TALLONE	Italy	1
	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Norway	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Denmark	1
	FRANCIS-JP-PL-EVERYDAY KNEE TO HEEL (SMALL)	Japan	1
	IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1

	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	New Zealand	1
	IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
	SCHOLL IN-BALANCE, EVERYDAY KNEE TO HEEL INSOLE	United Kingdom	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Finland	1
3076780	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	New Zealand	1
	SCHOLL INBALANCE INSOLE- EVERYDAY KNEE TO HEEL	United Kingdom	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (L)	Switzerland	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Finland	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (L)	Germany	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE EVERYDAY-DAL GINOCCHIO AL TALLONE	Italy	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (L)	Austria	1
	SEMELLE ANTI-DOULEUR GENOU ET TALON	France	1
	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	Australia	1
	IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Sweden	1

	SCHOLL IN BALANCE ORTHOTICS KNEE TO HEEL (M & L) / SCHOLL IN BALANCE ORTHOTICS HEEL (M & L)	Ireland	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Norway	1
	SCHOLL IN-BALANCE, EVERYDAY KNEE TO HEEL INSOLE	United Kingdom	1
	DR SCHOLL FRANCIS-JP-PL-EVERYDAY KNEE TO HEEL (LARGE)	Japan	1
	IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Denmark	1
3076785	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Austria	1
	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE, LOWER BACK INSOLE	United Kingdom	1
	SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Switzerland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1

	SCHOLL ORTHOTICS LOWER BACK (SMALL)	Ireland	1
	FRANCIS-JP-PL-LOWER BACK (SMALL)	Japan	1
	IN-BALANCE ZONA LOMBAR (S)	Portugal	1
	SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	New Zealand	1
	IN-BALANCE ZONA LUMBAR (S)	Spain	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Germany	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ZONA LOMBARE, LOMBALGIA	Italy	1
3076786	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
	IN-BALANCE ZONA LUMBAR (L)	Spain	1

	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ZONA LOMBARE, LOMBALGIA	Italy	1
	SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	New Zealand	1
	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE, LOWER BACK INSOLE	United Kingdom	1
	DR SCHOLL FRANCIS-JP-PL-LOWER BACK (LARGE)	Japan	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Germany	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Austria	1
	IN-BALANCE ZONA LOMBAR (L)	Portugal	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Switzerland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1
8312954	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1

DR SCHOLL FRANCIS-JP-PL-LOWER BACK (MEDIUM)	Japan	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Austria	1
SCHOLL IN-BALANCE, LOWER BACK INSOLE	United Kingdom	1
IN-BALANCE ZONA LUMBAR (M)	Spain	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1
SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	New Zealand	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Germany	1
SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM UNTEREN RÜCKEN	Switzerland	1
IN-BALANCE ZONA LOMBAR (M)	Portugal	1

	SCHOLL IN-BALANCE LOWER BACK ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ZONA LOMBARE, LOMBALGIA	Italy	1
	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
8312956	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Austria	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Germany	1
	SCHOLL IN-BALANCE EINLEGESOHLN BEI SCHMERZEN IM FUSSGEWÖLB	Switzerland	1
	IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1
	SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	New Zealand	1
	SCHOLL OTHORTICS BALL OF FOOT & ARCH (MEDIUM)	Ireland	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_ARCO PLANTARE, PIEDE PIATTO	Italy	1
	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Sweden	1



	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Finland	1
	IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Denmark	1
	SCHOLL IN-BALANCE ARCH ORTHOTIC INSOLE	Australia	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_LÄNDRYGG/LÆND/KORSRYGG/ALASELKÄ + SCHOLL IN-BALANCE PAIN RELIEF INSOLES_FOTVALV/SVANG/FOTBUE/JALKAHOLVI	Norway	1
	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1
	SCHOLL IN-BALANCE, ARCH INSOLE	United Kingdom	1
8312957	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/ HÆL/ KANTAPÄÄ (M)	Finland	1
	SCHOLL IN BALANCE ORTHOTICS KNEE TO HEEL (M & L) / SCHOLL IN BALANCE ORTHOTICS HEEL (M & L)	Ireland	1
	SCHOLL IN-BALANCE, HEEL INSOLE	United Kingdom	1
	IN-BALANCE TOBILLO Y TALÓN (M)	Spain	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆL/KANTAPÄÄ	Denmark	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	Australia	1
	BRANȚURI PENTRU AMELIORAREA DURERII	Romania	1

	SCHOLL IN-BALANCE PAIN RELIEF INSOLES, HÄL/HÆL/KANTAPÄÄ (M)	Norway	1
	SCHOLL IN-BALANCE PAIN RELIEF INSOLES_HÄL/HÆL/KANTAPÄÄ (M)	Sweden	1
	IN-BALANCE CALCANHAR E TORNOZELO (M)	Portugal	1
	SCHOLL IN-BALANCE DERÉKFÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE LÁBBOLTOZAT FÁJDALMAT ENYHÍTŐ TALPBETÉT; SCHOLL IN-BALANCE SAROK FÁJDALMAT ENYHÍTŐ TALPBETÉT	Hungary	1
	SCHOLL INBALANCE INSOLE- EVERYDAY KNEE TO HEEL	United Kingdom	1
	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE_TALLONE, TALLONITE, TENDINE D'ACHILLE	Italy	1
	SCHOLL IN-BALANCE HEEL ORTHOTIC INSOLE	New Zealand	1
8312958	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Norway	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (M)	Switzerland	1
	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	Australia	1
	DR SCHOLL FRANCIS-JP-PL-EVERYDAY KNEE TO HEEL (MEDIUM)	Japan	1
	SCHOLL IN BALANCE ORTHOTICS KNEE TO HEEL (M & L) / SCHOLL IN BALANCE ORTHOTICS HEEL (M & L)	Ireland	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Denmark	1

	SCHOLL IN-BALANCE PLANTARE SOLLIEVO DOLORE EVERYDAY-DAL GINOCCHIO AL TALLONE	Italy	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Finland	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (M)	Germany	1
	SCHOLL IN-BALANCE, EVERYDAY KNEE TO HEEL INSOLE	United Kingdom	1
	SCHOLL IN-BALANCE EVERYDAY KNEE TO HEEL ORTHOTIC INSOLE	New Zealand	1
	SCHOLL IN-BALANCE EINLAGEN BEI SCHMERZEN VON KNIE BIS FERSE (M)	Austria	1
	SEMELLE ANTI-DOULEUR GENOU ET TALON	France	1
	IN-BALANCE USO DIÁRIO JOELHO E CALCANHAR	Portugal	1
	SCHOLL IN-BALANCE™ PAIN RELIEF KNEE TO HEEL INSOLES	Sweden	1
	IN-BALANCE USO DIARIO RODILLA Y TALÓN	Spain	1
	SCHOLL INBALANCE INSOLE- EVERYDAY KNEE TO HEEL	United Kingdom	1
3076784	EINLAGEN BEI PLANTAR FASZIITIS	Germany	1
	EINLAGEN BEI PLANTAR FASZIITIS	Austria	1
	SEMELLES ANTI-DOULEUR FASCIITE PLANTAIRE	France	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	UK	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	Ireland	1
	FASCITE PLANTARE PLANTARE SOLLIEVO DOLORE	Italy	1

	FASCITIS PLANTAR PLANTILLA PARA EL ALIVIO DEL DOLOR	Spain	1
	FASCITE PLANTAR PALMILHA DE ALÍVIO DA DOR	Portugal	1
	IN BALANCE PLANTAR FASCIITIS SMERTE LETTELSE INDSAL	Denmark	1
	IN BALANCE PLANTAARIFASKIITIN KIPUA LIEVITTAVAT POHJALLISET	Finland	1
	IN BALANCE PLANTAR FASCIITIS FOTINLAGG FOR SMARTLINDRING	Sweden	1
	IN BALANCE VERKJASTILLANDI INNLEGG	Iceland	1
	IN BALANCE PLANTAR FASCIITT SMERTELINDRING INNERSALE	Norway	1
8312960	EINLAGEN BEI PLANTAR FASZIITIS	Germany	1
	EINLAGEN BEI PLANTAR FASZIITIS	Austria	1
	SEMELLES ANTI-DOULEUR FASCIITE PLANTAIRE	France	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	UK	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	Ireland	1
	FASCITE PLANTARE PLANTARE SOLLIEVO DOLORE	Italy	1
	FASCITIS PLANTAR PLANTILLA PARA EL ALIVIO DEL DOLOR	Spain	1
	FASCITE PLANTAR PALMILHA DE ALÍVIO DA DOR	Portugal	1
	IN BALANCE PLANTAR FASCIITIS SMERTE LETTELSE INDSAL	Denmark	1

	IN BALANCE PLANTAARIFASKIITIN KIPUA LIEVITTAVAT POHJALLISET	Finland	1
	IN BALANCE PLANTAR FASCIITIS FOTINLAGG FOR SMARTLINDRING	Sweden	1
	IN BALANCE VERKJASTILLANDI INNLEGG	Iceland	1
	IN BALANCE PLANTAR FASCIITT SMERTELINDRING INNERSALE	Norway	1
3076783	EINLAGEN BEI PLANTAR FASZIITIS	Germany	1
	EINLAGEN BEI PLANTAR FASZIITIS	Austria	1
	SEMELLES ANTI-DOULEUR FASCIITE PLANTAIRE	France	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	UK	1
	IN -BALANCE PLANTAR FASCIITS PAIN RELIEF INSOLE	Ireland	1
	FASCITE PLANTARE PLANTARE SOLLIEVO DOLORE	Italy	1
	FASCITIS PLANTAR PLANTILLA PARA EL ALIVIO DEL DOLOR	Spain	1
	FASCITE PLANTAR PALMILHA DE ALÍVIO DA DOR	Portugal	1
	IN BALANCE PLANTAR FASCIITIS SMERTE LETTEELSE INDSAL	Denmark	1
	IN BALANCE PLANTAARIFASKIITIN KIPUA LIEVITTAVAT POHJALLISET	Finland	1
	IN BALANCE PLANTAR FASCIITIS FOTINLAGG FOR SMARTLINDRING	Sweden	1
	IN BALANCE VERKJASTILLANDI INNLEGG	Iceland	1
	IN BALANCE PLANTAR FASCIITT SMERTELINDRING INNERSALE	Norway	1

### Appendix 3: Languages accepted in the Member States

Country	Official and National Languages
Albania	Albanian
Andorra	Catalan
Austria	German, Slovene, Croatian and
Belarus	Belarusian, Russian
Belgium	Dutch, French, German
Bosnia & Herzegovina	Bosnian, Croatian, Serbian
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek, Turkish, English
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Faroe Islands	Faroese, Danish
Finland	Finnish, Swedish
France	French
Germany	German
Gibraltar	English
Greece	Greek
Greenland	Greenlandic Inuktitut, Danish
Hungary	Hungarian
Iceland	Icelandic
Ireland	Irish, English
Italy	Italian
Latvia	Latvian
Liechtenstein	German
Lithuania	Lithuanian
Luxembourg	Luxembourgish, French, German
Macedonia, Rep. of	Macedonian, Albanian
Malta	Maltese
Moldova	Moldovan
Monaco	French
Montenegro	Serbo-Croatian

Netherlands	Dutch
Norway	Norwegian
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Russian Federation	Russian
San Marino	Italian
Serbia	Serbian, Albanian
Slovakia	Slovak
Slovenia	Slovenian
Spain	Spanish, Catalan, Galician, Basque
Sweden	Swedish
Switzerland	German, French, Italian, Romansch
Turkey	Turkish
Ukraine	Ukrainian
United Kingdom	English
Vatican City State	Latin, Italian