

Declaration of Conformity

for Formthotics Foot Orthotic Insoles

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Formthotics Foot Orthotic Insoles
Legal Manufacturer: (Name on Label)	Foot Science International Limited, 26 Dakota Cres, Christchurch 8042, New Zealand
Manufacturers SRN:	NZ-MF-000044443
Basic UDI-DI:	941943000001C2
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Formthotics Foot Orthotic Insoles are used by Podiatrists and other health professionals to modify footwear in treating various painful conditions of the foot and leg
Regulation (EU) 2017/745 Classification:	Class I, Rule 1
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234

Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the Regulation (EU) 2017/745.
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Name Anne Arndt **Position** PRRC

Signed *Anne Arndt*
Anne Arndt (Feb 2, 2026 13:02:38 GMT+13) **Date** 28/01/2026 **Place** Christchurch, NZ

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 20417:2021	Medical devices. Information supplied by the manufacturer
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
ISO 10093-1	Biological evaluation of medical devices

Appendix II – Product Listing/Schedule

Legacy Catalogue Number	Catalogue Number	Device Name	EMDM Code	GMDN Code
3dApSa-BI-L	3d-01-ApSa-BI-L	3D Arch Pads Blue Adh L	Y061203	41575
3dApSa-BI-M	3d-01-ApSa-BI-M	3D Arch Pads Blue Adh M	Y061203	41575
3dApSa-BI-S	3d-01-ApSa-BI-S	3D Arch Pads Blue Adh S	Y061203	41575
3dHrSa-Re-L	3d-01-HrSa-Re-L	3D Heel Raisers Red Adh L	Y061203	41575
3dHrSa-Re-M	3d-01-HrSa-Re-M	3D Heel Raisers Red Adh M	Y061203	41575
3dHrSa-Re-S	3d-01-HrSa-Re-S	3D Heel Raisers Red Adh S	Y061203	41575
3dRFwSa-Gr-L	3d-01-RFwSa-Gr-L	3D Rev Forefoot Wedge Adh L	Y061203	41575
3dRFwSa-Gr-M	3d-01-RFwSa-Gr-M	3D Rev Forefoot Wedge Adh M	Y061203	41575
3dRFwSa-Gr-S	3d-01-RFwSa-Gr-S	3D Rev Forefoot Wedge Adh S	Y061203	41575
3dTRwSa-Or-L	3d-01-TrwSa-Or-L	3D Tri-plane Rearfoot Wedge Adh L	Y061203	41575
3dTRwSa-Or-M	3d-01-TrwSa-Or-M	3D Tri-plane Rearfoot Wedge Adh M	Y061203	41575
3dTRwSa-Or-S	3d-01-TrwSa-Or-S	3D Tri-plane Rearfoot Wedge Adh S	Y061203	41575
A4mPl-Re-L	A-01-4mPl-Re-L	Low Heel Raise Red Plain L	Y061203	59098
A4mPl-Re-M	A-01-4mPl-Re-M	Low Heel Raise Red Plain M	Y061203	59098
A4mPl-Re-S	A-01-4mPl-Re-S	Low Heel Raise Red Plain S	Y061203	59098
A4mSa-Re-L	A-01-4mSa-Re-L	Low Heel Raise Red Adh L	Y061203	59098
A4mSa-Re-M	A-01-4mSa-Re-M	Low Heel Raise Red Adh M	Y061203	59098
A4mSa-Re-S	A-01-4mSa-Re-S	Low Heel Raise Red Adh S	Y061203	59098
A6mPl-Re-L	A-01-6mPl-Re-L	High Heel Raise Red Plain L	Y061203	59098
A6mPl-Re-M	A-01-6mPl-Re-M	High Heel Raise Red Plain M	Y061203	59098
A6mPl-Re-S	A-01-6mPl-Re-S	High Heel Raise Red Plain S	Y061203	59098
A6mSa-Re-L	A-01-6mSA-Re-L	High Heel Raise Red Adh L	Y061203	59098
A6mSa-Re-M	A-01-6mSA-Re-M	High Heel Raise Red Adh M	Y061203	59098
A6mSa-Re-S	A-01-6mSA-Re-S	High Heel Raise Red Adh S	Y061203	59098
AApPl-Re-L	A-01-ApPl-Re-L	Hard Arch Pad Red Plain L	Y061203	41575
AApPl-Re-M	A-01-ApPl-Re-M	Hard Arch Pad Red Plain M	Y061203	41575
AApPl-Re-S	A-01-ApPl-Re-S	Hard Arch Pad Red Plain S	Y061203	41575
AApSa-Re-L	A-01-ApSA-Re-L	Hard Arch Pad Red Adh L	Y061203	41575

AApSa-Re-M	A-01-ApSA-Re-M	Hard Arch Pad Red Adh M	Y061203	41575
AApSa-Re-S	A-01-ApSA-Re-S	Hard Arch Pad Red Adh S	Y061203	41575
AEwPI-Bk-L	A-01-EwPI-Bk-L	Firm Ext Wedge Black Plain L	Y061203	59098
AEwPI-Bk-M	A-01-EwPI-Bk-M	Firm Ext Wedge Black Plain M	Y061203	59098
AEwPI-Bk-S	A-01-EwPI-Bk-S	Firm Ext Wedge Black Plain S	Y061203	59098
AEwPI-BI-L	A-01-EwPI-BI-L	Med Ext Wedge Blue Plain L	Y061203	59098
AEwPI-BI-M	A-01-EwPI-BI-M	Med Ext Wedge Blue Plain M	Y061203	59098
AEwPI-BI-S	A-01-EwPI-BI-S	Med Ext Wedge Blue Plain S	Y061203	59098
AEwSa-Bk-L	A-01-EwSA-Bk-L	Firm Ext Wedge Black Adh L	Y061203	59098
AEwSa-Bk-M	A-01-EwSA-Bk-M	Firm Ext Wedge Black Adh M	Y061203	59098
AEwSa-Bk-S	A-01-EwSA-Bk-S	Firm Ext Wedge Black Adh S	Y061203	59098
AEwSa-BI-L	A-01-EwSA-BI-L	Med Ext Wedge Blue Adh L	Y061203	59098
AEwSa-BI-M	A-01-EwSA-BI-M	Med Ext Wedge Blue Adh M	Y061203	59098
AEwSa-BI-S	A-01-EwSA-BI-S	Med Ext Wedge Blue Adh S	Y061203	59098
AMdPI-Gr-1	A-01-MdPI-Gr-1	Met Domes Grey Plain 1	Y061203	41575
AMdPI-Gr-2	A-01-MdPI-Gr-2	Met Domes Grey Plain 2	Y061203	41575
AMdSa-Bk-1	A-01-MdSA-Bk-1	Firm Met Domes Black Adh 1	Y061203	41575
AMdSa-Bk-2	A-01-MdSA-Bk-2	Firm Met Domes Black Adh 2	Y061203	41575
AMdSa-BI-1	A-01-MdSA-BI-1	Med Met Domes Blue Adh 1	Y061203	41575
AMdSa-BI-2	A-01-MdSA-BI-2	Med Met Domes Blue Adh 2	Y061203	41575
ARwPI-Bk-L	A-01-RwPI-Bk-L	Firm Rearfoot Wedge Black Plain L	Y061203	59098
ARwPI-Bk-M	A-01-RwPI-Bk-M	Firm Rearfoot Wedge Black Plain M	Y061203	59098
ARwPI-Bk-S	A-01-RwPI-Bk-S	Firm Rearfoot Wedge Black Plain S	Y061203	59098
ARwPI-BI-L	A-01-RwPI-BI-L	Med Rearfoot Wedge Blue Plain L	Y061203	59098
ARwPI-BI-M	A-01-RwPI-BI-M	Med Rearfoot Wedge Blue Plain M	Y061203	59098
ARwPI-BI-S	A-01-RwPI-BI-S	Med Rearfoot Wedge Blue Plain S	Y061203	59098
ARwSa-Bk-L	A-01-RwSA-Bk-L	Firm Rearfoot Wedge Black Adh L	Y061203	59098
ARwSa-Bk-M	A-01-RwSA-Bk-M	Firm Rearfoot Wedge Black Adh M	Y061203	59098
ARwSa-Bk-S	A-01-RwSA-Bk-S	Firm Rearfoot Wedge Black Adh S	Y061203	59098
ARwSa-BI-L	A-01-RwSA-BI-L	Med Rearfoot Wedge Blue Adh L	Y061203	59098
ARwSa-BI-M	A-01-RwSA-BI-M	Med Rearfoot Wedge Blue Adh M	Y061203	59098
ARwSa-BI-S	A-01-RwSA-BI-S	Med Rearfoot Wedge Blue Adh S	Y061203	59098

A-01-WsSa-BI-S	A-01-WsSa-BI-S	Wedge Strip Blue Adh S	Y061203	59098
FM3qDmB-Rb-XXS	FM01-3qDmB-Rb-2S	Medical 3/4 Dual Medium XXS	Y061203	59098
FM3qDmB-Rb-L	FM01-3qDmB-Rb-LA	Medical 3/4 Dual Medium L	Y061203	59098
FM3qDmB-Rb-M	FM01-3qDmB-Rb-ME	Medical 3/4 Dual Medium M	Y061203	59098
FM3qDmB-Rb-S	FM01-3qDmB-Rb-SM	Medical 3/4 Dual Medium S	Y061203	59098
FM3qDmB-Rb-XL	FM01-3qDmB-Rb-XL	Medical 3/4 Dual Medium XL	Y061203	59098
FM3qDmB-Rb-XS	FM01-3qDmB-Rb-XS	Medical 3/4 Dual Medium XS	Y061203	59098
FMcfShB-Re-XXS	FM01-CfShB-Re-2S	Medical Comfort Single Hard XXS	Y061203	59098
FMcfShB-Re-L	FM01-CfShB-Re-LA	Medical Comfort Single Hard L	Y061203	59098
FMcfShB-Re-M	FM01-CfShB-Re-ME	Medical Comfort Single Hard M	Y061203	59098
FMcfShB-Re-S	FM01-CfShB-Re-SM	Medical Comfort Single Hard S	Y061203	59098
FMcfShB-Re-XL	FM01-CfShB-Re-XL	Medical Comfort Single Hard XL	Y061203	59098
FMcfShB-Re-XS	FM01-CfShB-Re-XS	Medical Comfort Single Hard XS	Y061203	59098
FMcfSmB-Ch-XXS	FM01-CfSmB-Ch-2S	Medical Comfort Single Medium XXS	Y061203	59098
FMcfSmB-Ch-L	FM01-CfSmB-Ch-LA	Medical Comfort Single Medium L	Y061203	59098
FMcfSmB-Ch-M	FM01-CfSmB-Ch-ME	Medical Comfort Single Medium M	Y061203	59098
FMcfSmB-Ch-S	FM01-CfSmB-Ch-SM	Medical Comfort Single Medium S	Y061203	59098
FMcfSmB-Ch-XL	FM01-CfSmB-Ch-XL	Medical Comfort Single Medium XL	Y061203	59098
FMcfSmB-Ch-XS	FM01-CfSmB-Ch-XS	Medical Comfort Single Medium XS	Y061203	59098
FMJrC-Db-01	FM01-JrSmC-Db-01	Medical Junior 01	Y061203	59098
FMJrC-Db-02	FM01-JrSmC-Db-02	Medical Junior 02	Y061203	59098
FMJrC-Db-03	FM01-JrSmC-Db-03	Medical Junior 03	Y061203	59098
FMJrC-Db-04	FM01-JrSmC-Db-04	Medical Junior 04	Y061203	59098
FMLpDhA-Rr-XXL	FM01-LpDhA-Rr-2L	Medical Low Profile Dual Hard XXL	Y061203	59098
FMLpDhB-Rr-XXS	FM01-LpDhB-Rr-2S	Medical Low Profile Dual Hard XXS	Y061203	59098
FMLpDhB-Rr-L	FM01-LpDhB-Rr-LA	Medical Low Profile Dual Hard L	Y061203	59098
FMLpDhB-Rr-M	FM01-LpDhB-Rr-ME	Medical Low Profile Dual Hard M	Y061203	59098
FMLpDhB-Rr-S	FM01-LpDhB-Rr-SM	Medical Low Profile Dual Hard S	Y061203	59098
FMLpDhB-Rr-XL	FM01-LpDhB-Rr-XL	Medical Low Profile Dual Hard XL	Y061203	59098
FMLpDhB-Rr-XS	FM01-LpDhB-Rr-XS	Medical Low Profile Dual Hard XS	Y061203	59098
FM01-LpDmA-Bg-2L	FM01-LpDmA-Bg-2L	Medical Low Profile Dual Medium XXL	Y061203	59098
FM01-LpDmB-Bg-2S	FM01-LpDmB-Bg-2S	Medical Low Profile Dual Medium XXS	Y061203	59098

FM01-LpDmB-Bg-LA	FM01-LpDmB-Bg-LA	Medical Low Profile Dual Medium L	Y061203	59098
FM01-LpDmB-Bg-ME	FM01-LpDmB-Bg-ME	Medical Low Profile Dual Medium M	Y061203	59098
FM01-LpDmB-Bg-SM	FM01-LpDmB-Bg-SM	Medical Low Profile Dual Medium S	Y061203	59098
FM01-LpDmB-Bg-XL	FM01-LpDmB-Bg-XL	Medical Low Profile Dual Medium XL	Y061203	59098
FM01-LpDmB-Bg-XS	FM01-LpDmB-Bg-XS	Medical Low Profile Dual Medium XS	Y061203	59098
FMLvSfA-Bk-XXL	FM01-LvSfA-Bk-2L	Medical Low Volume Single Firm XXL	Y061203	59098
FMLvSfB-Bk-XXS	FM01-LvSfB-Bk-2S	Medical Low Volume Single Firm XXS	Y061203	59098
FMLvSfB-Bk-L	FM01-LvSfB-Bk-LA	Medical Low Volume Single Firm L	Y061203	59098
FMLvSfB-Bk-M	FM01-LvSfB-Bk-ME	Medical Low Volume Single Firm M	Y061203	59098
FMLvSfB-Bk-S	FM01-LvSfB-Bk-SM	Medical Low Volume Single Firm S	Y061203	59098
FMLvSfB-Bk-XL	FM01-LvSfB-Bk-XL	Medical Low Volume Single Firm XL	Y061203	59098
FMLvSfB-Bk-XS	FM01-LvSfB-Bk-XS	Medical Low Volume Single Firm XS	Y061203	59098
FMLvSmAp-Gr-XXL	FM01-LvSmApGr-2L	Medical L/V Single Medium (P) XXL	Y061203	59098
FMLvSmBp-Gr-XXS	FM01-LvSmBpGr-2S	Medical L/V Single Medium (P) XXS	Y061203	59098
FMLvSmBp-Gr-L	FM01-LvSmBpGr-LA	Medical L/V Single Medium (P) L	Y061203	59098
FMLvSmBp-Gr-M	FM01-LvSmBpGr-ME	Medical L/V Single Medium (P) M	Y061203	59098
FMLvSmBp-Gr-S	FM01-LvSmBpGr-SM	Medical L/V Single Medium (P) S	Y061203	59098
FMLvSmBp-Gr-XL	FM01-LvSmBpGr-XL	Medical L/V Single Medium (P) XL	Y061203	59098
FMLvSmBp-Gr-XS	FM01-LvSmBpGr-XS	Medical L/V Single Medium (P) XS	Y061203	59098
FMOOrDhA-Rr-XXL	FM01-OrDhA-Rr-2L	Medical Original Dual Hard XXL	Y061203	59098
FMOOrDhA-Rr-XXS	FM01-OrDhA-Rr-2S	Medical Original Dual Hard XXS	Y061203	59098
FMOOrDhA-Rr-L	FM01-OrDhA-Rr-LA	Medical Original Dual Hard L	Y061203	59098
FMOOrDhA-Rr-M	FM01-OrDhA-Rr-ME	Medical Original Dual Hard M	Y061203	59098
FMOOrDhA-Rr-S	FM01-OrDhA-Rr-SM	Medical Original Dual Hard S	Y061203	59098
FMOOrDhA-Rr-XL	FM01-OrDhA-Rr-XL	Medical Original Dual Hard XL	Y061203	59098
FMOOrDhA-Rr-XS	FM01-OrDhA-Rr-XS	Medical Original Dual Hard XS	Y061203	59098
FMOOrDmAp-Bt-XXL	FM01-OrDmApBt-2L	Medical Original Dual Medium (P) XXL	Y061203	59098
FMOOrDmAp-Bt-XXS	FM01-OrDmApBt-2S	Medical Original Dual Medium (P) XXS	Y061203	59098
FMOOrDmAp-Bt-L	FM01-OrDmApBt-LA	Medical Original Dual Medium (P) L	Y061203	59098
FMOOrDmAp-Bt-M	FM01-OrDmApBt-ME	Medical Original Dual Medium (P) M	Y061203	59098
FMOOrDmAp-Bt-S	FM01-OrDmApBt-SM	Medical Original Dual Medium (P) S	Y061203	59098
FMOOrDmAp-Bt-XL	FM01-OrDmApBt-XL	Medical Original Dual Medium (P) XL	Y061203	59098

FMOOrDmAp-Bt-XS	FM01-OrDmApBt-XS	Medical Original Dual Medium (P) XS	Y061203	59098
FMOOrDmA-Rb-XXL	FM01-OrDmA-Rb-2L	Medical Original Dual Medium XXL	Y061203	59098
FMOOrDmA-Rb-XXS	FM01-OrDmA-Rb-2S	Medical Original Dual Medium XXS	Y061203	59098
FMOOrDmA-Rb-L	FM01-OrDmA-Rb-LA	Medical Original Dual Medium L	Y061203	59098
FMOOrDmA-Rb-M	FM01-OrDmA-Rb-ME	Medical Original Dual Medium M	Y061203	59098
FMOOrDmA-Rb-S	FM01-OrDmA-Rb-SM	Medical Original Dual Medium S	Y061203	59098
FMOOrDmA-Rb-XL	FM01-OrDmA-Rb-XL	Medical Original Dual Medium XL	Y061203	59098
FMOOrDmA-Rb-XS	FM01-OrDmA-Rb-XS	Medical Original Dual Medium XS	Y061203	59098
FMOOrDmB-Rb-Y1	FM01-OrDmB-Rb-Y1	Medical Original Dual Medium Y1	Y061203	59098
FMOOrDmB-Rb-Y2	FM01-OrDmB-Rb-Y2	Medical Original Dual Medium Y2	Y061203	59098
FMOOrDmB-Rb-Y3	FM01-OrDmB-Rb-Y3	Medical Original Dual Medium Y3	Y061203	59098
FM01-OrDuA-Pn-2L	FM01-OrDuA-Pn-2L	Medical Original Dual Ultra XXL	Y061203	59098
FM01-OrDuA-Pn-LA	FM01-OrDuA-Pn-LA	Medical Original Dual Ultra L	Y061203	59098
FM01-OrDuA-Pn-ME	FM01-OrDuA-Pn-ME	Medical Original Dual Ultra M	Y061203	59098
FM01-OrDuA-Pn-SM	FM01-OrDuA-Pn-SM	Medical Original Dual Ultra S	Y061203	59098
FM01-OrDuA-Pn-XL	FM01-OrDuA-Pn-XL	Medical Original Dual Ultra XL	Y061203	59098
FM01-OrDuA-Pn-XS	FM01-OrDuA-Pn-XS	Medical Original Dual Ultra XS	Y061203	59098
FMOOrSfA-Bk-XXL	FM01-OrSfA-Bk-2L	Medical Original Single Firm XXL	Y061203	59098
FMOOrSfA-Bk-XXS	FM01-OrSfA-Bk-2S	Medical Original Single Firm XXS	Y061203	59098
FMOOrSfA-Bk-L	FM01-OrSfA-Bk-LA	Medical Original Single Firm L	Y061203	59098
FMOOrSfA-Bk-M	FM01-OrSfA-Bk-ME	Medical Original Single Firm M	Y061203	59098
FMOOrSfA-Bk-S	FM01-OrSfA-Bk-SM	Medical Original Single Firm S	Y061203	59098
FMOOrSfA-Bk-XL	FM01-OrSfA-Bk-XL	Medical Original Single Firm XL	Y061203	59098
FMOOrSfA-Bk-XS	FM01-OrSfA-Bk-XS	Medical Original Single Firm XS	Y061203	59098
FMOOrShA-Re-XXL	FM01-OrShA-Re-2L	Medical Original Single Hard XXL	Y061203	59098
FMOOrShA-Re-XXS	FM01-OrShA-Re-2S	Medical Original Single Hard XXS	Y061203	59098
FMOOrShA-Re-XXXL	FM01-OrShA-Re-3L	Medical Original Single Hard XXXL	Y061203	59098
FMOOrShA-Re-L	FM01-OrShA-Re-LA	Medical Original Single Hard L	Y061203	59098
FMOOrShA-Re-M	FM01-OrShA-Re-ME	Medical Original Single Hard M	Y061203	59098
FMOOrShA-Re-S	FM01-OrShA-Re-SM	Medical Original Single Hard S	Y061203	59098
FMOOrShA-Re-XL	FM01-OrShA-Re-XL	Medical Original Single Hard XL	Y061203	59098
FMOOrShA-Re-XS	FM01-OrShA-Re-XS	Medical Original Single Hard XS	Y061203	59098

FMOOrSmA-BI-XXL	FM01-OrSmA-BI-2L	Medical Original Single Medium XXL	Y061203	59098
FMOOrSmA-BI-XXS	FM01-OrSmA-BI-2S	Medical Original Single Medium XXS	Y061203	59098
FMOOrSmA-BI-XXXL	FM01-OrSmA-BI-3L	Medical Original Single Medium XXXL	Y061203	59098
FMOOrSmA-BI-L	FM01-OrSmA-BI-LA	Medical Original Single Medium L	Y061203	59098
FMOOrSmA-BI-M	FM01-OrSmA-BI-ME	Medical Original Single Medium M	Y061203	59098
FMOOrSmA-BI-S	FM01-OrSmA-BI-SM	Medical Original Single Medium S	Y061203	59098
FMOOrSmA-BI-XL	FM01-OrSmA-BI-XL	Medical Original Single Medium XL	Y061203	59098
FMOOrSmA-BI-XS	FM01-OrSmA-BI-XS	Medical Original Single Medium XS	Y061203	59098
FMOOrSmB-BI-Y1	FM01-OrSmB-BI-Y1	Medical Original Single Medium Y1	Y061203	59098
FMOOrSmB-BI-Y2	FM01-OrSmB-BI-Y2	Medical Original Single Medium Y2	Y061203	59098
FMOOrSmB-BI-Y3	FM01-OrSmB-BI-Y3	Medical Original Single Medium Y3	Y061203	59098
FMOOrSpA-Cb-XXL	FM01-OrSpA-Cb-2L	Medical Original ShockStop XXL	Y061203	59098
FMOOrSpA-Cb-XXS	FM01-OrSpA-Cb-2S	Medical Original ShockStop XXS	Y061203	59098
FMOOrSpA-Cb-L	FM01-OrSpA-Cb-LA	Medical Original ShockStop L	Y061203	59098
FMOOrSpA-Cb-M	FM01-OrSpA-Cb-ME	Medical Original ShockStop M	Y061203	59098
FMOOrSpA-Cb-S	FM01-OrSpA-Cb-SM	Medical Original ShockStop S	Y061203	59098
FMOOrSpA-Cb-XL	FM01-OrSpA-Cb-XL	Medical Original ShockStop XL	Y061203	59098
FMOOrSpA-Cb-XS	FM01-OrSpA-Cb-XS	Medical Original ShockStop XS	Y061203	59098
FMOOrSsA-Bu-XXL	FM01-OrSsA-Bu-2L	Medical Original Single Soft XXL	Y061203	59098
FMOOrSsA-Bu-XXS	FM01-OrSsA-Bu-2S	Medical Original Single Soft XXS	Y061203	59098
FMOOrSsA-Bu-L	FM01-OrSsA-Bu-LA	Medical Original Single Soft L	Y061203	59098
FMOOrSsA-Bu-M	FM01-OrSsA-Bu-ME	Medical Original Single Soft M	Y061203	59098
FMOOrSsA-Bu-S	FM01-OrSsA-Bu-SM	Medical Original Single Soft S	Y061203	59098
FMOOrSsA-Bu-XL	FM01-OrSsA-Bu-XL	Medical Original Single Soft XL	Y061203	59098
FMOOrSsA-Bu-XS	FM01-OrSsA-Bu-XS	Medical Original Single Soft XS	Y061203	59098
FM01-OrSuA-Na-2L	FM01-OrSuA-Na-2L	Medical Original Single Ultra XXL	Y061203	59098
FM01-OrSuA-Na-LA	FM01-OrSuA-Na-LA	Medical Original Single Ultra L	Y061203	59098
FM01-OrSuA-Na-ME	FM01-OrSuA-Na-ME	Medical Original Single Ultra M	Y061203	59098
FM01-OrSuA-Na-SM	FM01-OrSuA-Na-SM	Medical Original Single Ultra S	Y061203	59098
FM01-OrSuA-Na-XL	FM01-OrSuA-Na-XL	Medical Original Single Ultra XL	Y061203	59098
FM01-OrSuA-Na-XS	FM01-OrSuA-Na-XS	Medical Original Single Ultra XS	Y061203	59098
FMOOrXsA-Be-XXL	FM01-OrXsA-Be-2L	Medical Original Single X Soft XXL	Y061203	59098

FMOxSA-Be-XXS	FM01-OrXsA-Be-2S	Medical Original Single X Soft XXS	Y061203	59098
FMOxSA-Be-L	FM01-OrXsA-Be-LA	Medical Original Single X Soft L	Y061203	59098
FMOxSA-Be-M	FM01-OrXsA-Be-ME	Medical Original Single X Soft M	Y061203	59098
FMOxSA-Be-S	FM01-OrXsA-Be-SM	Medical Original Single X Soft S	Y061203	59098
FMOxSA-Be-XL	FM01-OrXsA-Be-XL	Medical Original Single X Soft XL	Y061203	59098
FMOxSA-Be-XS	FM01-OrXsA-Be-XS	Medical Original Single X Soft XS	Y061203	59098
FMOxSB-Be-Y1	FM01-OrXsB-Be-Y1	Medical Original Single X Soft Y1	Y061203	59098
FMOxSB-Be-Y2	FM01-OrXsB-Be-Y2	Medical Original Single X Soft Y2	Y061203	59098
FMOxSB-Be-Y3	FM01-OrXsB-Be-Y3	Medical Original Single X Soft Y3	Y061203	59098
FMSCSfA-Bk-XXL	FM01-SCSfA-Bk-2L	Medical Cycle Single Firm XXL	Y061203	59098
FMSCSfB-Bk-XXS	FM01-SCSfB-Bk-2S	Medical Cycle Single Firm XXS	Y061203	59098
FMSCSfB-Bk-L	FM01-SCSfB-Bk-LA	Medical Cycle Single Firm L	Y061203	59098
FMSCSfB-Bk-M	FM01-SCSfB-Bk-ME	Medical Cycle Single Firm M	Y061203	59098
FMSCSfB-Bk-S	FM01-SCSfB-Bk-SM	Medical Cycle Single Firm S	Y061203	59098
FMSCSfB-Bk-XL	FM01-SCSfB-Bk-XL	Medical Cycle Single Firm XL	Y061203	59098
FMSCSfB-Bk-XS	FM01-SCSfB-Bk-XS	Medical Cycle Single Firm XS	Y061203	59098
FM01-SfDmApBg-2L	FM01-SfDmApBg-2L	Medical Slim Fit Dual Medium (P) XXL	Y061203	59098
FM01-SfDmBpBg-LA	FM01-SfDmBpBg-LA	Medical Slim Fit Dual Medium (P) L	Y061203	59098
FM01-SfDmBpBg-ME	FM01-SfDmBpBg-ME	Medical Slim Fit Dual Medium (P) M	Y061203	59098
FM01-SfDmBpBg-SM	FM01-SfDmBpBg-SM	Medical Slim Fit Dual Medium (P) S	Y061203	59098
FM01-SfDmBpBg-XL	FM01-SfDmBpBg-XL	Medical Slim Fit Dual Medium (P) XL	Y061203	59098
FM01-SfDmBpBg-XS	FM01-SfDmBpBg-XS	Medical Slim Fit Dual Medium (P) XS	Y061203	59098
FM01-WfDmA-Bg-2L	FM01-WfDmA-Bg-2L	Medical Widefit Dual Medium XXL	Y061203	59098
FM01-WfDmA-Bg-2S	FM01-WfDmA-Bg-2S	Medical Widefit Dual Medium XXS	Y061203	59098
FM01-WfDmA-Bg-LA	FM01-WfDmA-Bg-LA	Medical Widefit Dual Medium L	Y061203	59098
FM01-WfDmA-Bg-ME	FM01-WfDmA-Bg-ME	Medical Widefit Dual Medium M	Y061203	59098
FM01-WfDmA-Bg-SM	FM01-WfDmA-Bg-SM	Medical Widefit Dual Medium S	Y061203	59098
FM01-WfDmA-Bg-XL	FM01-WfDmA-Bg-XL	Medical Widefit Dual Medium XL	Y061203	59098
FM01-WfDmA-Bg-XS	FM01-WfDmA-Bg-XS	Medical Widefit Dual Medium XS	Y061203	59098
FYDuDhB-Rb-Y1	FY01-DuDhB-Rb-Y1	Youth Dual Y1	Y061203	59098
FYDuDhB-Rb-Y2	FY01-DuDhB-Rb-Y2	Youth Dual Y2	Y061203	59098
FYDuDhB-Rb-Y3	FY01-DuDhB-Rb-Y3	Youth Dual Y3	Y061203	59098

FM06-OrShA-Re-2L	FM06-OrShA-Re-2L	Medical Original Single Hard XXL - NB	Y061203	59098
FM06-OrShA-Re-2S	FM06-OrShA-Re-2S	Medical Original Single Hard XXS - NB	Y061203	59098
FM06-OrShA-Re-LA	FM06-OrShA-Re-LA	Medical Original Single Hard L - NB	Y061203	59098
FM06-OrShA-Re-ME	FM06-OrShA-Re-ME	Medical Original Single Hard M - NB	Y061203	59098
FM06-OrShA-Re-SM	FM06-OrShA-Re-SM	Medical Original Single Hard S - NB	Y061203	59098
FM06-OrShA-Re-XL	FM06-OrShA-Re-XL	Medical Original Single Hard XL - NB	Y061203	59098
FM06-OrShA-Re-XS	FM06-OrShA-Re-XS	Medical Original Single Hard XS - NB	Y061203	59098

Version History

Version	Compiled by	Date	Description
1.0	H McIntyre	2/10/2019	First issue
2.0	H McIntyre	16/07/2021	Updated to include UDI-DI and update model range
3.0	H McIntyre	28/10/2021	Updated to new template
3.1	H McIntyre	30/11/2021	Updated manufacturer name to include Limited, added applicable rule to MDR classification, updated Applicable Standards list
4	H McIntyre	05/10/2023	Updated 14971:2012 to updated version 14971:2019
5	H McIntyre	4/04/2024	Updated with 'sole responsibility' statement and added reference to EN ISO 15223-1:2021
6	H McIntyre	01/05/2024	Updated to include new Formthotic Ultra Product
7	N Belsham	24/06/2024	Updated Signatory
8	N Belsham	04/10/2024	Updated Signatory and SRN number
9	N Belsham	06/06/2025	Updated with new variation of product B/G and GMDN Codes/FM06 Codes
10	N Belsham	28/01/2026	Legacy codes Listed for reference

Declaration of Conformity

for Express Ready-Fit Orthotic Insoles

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Express Ready-Fit Orthotic Insoles
Legal Manufacturer: (Name on Label)	Foot Science International Limited, 26 Dakota Cres, Christchurch 8042, New Zealand
Manufacturers SRN:	NZ-MF-000044443
Basic UDI-DI:	941943000002C4
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Express Ready-Fit Orthotic Insoles are used by Podiatrists and other health professionals to modify footwear in treating various painful conditions of the foot and leg
Regulation (EU) 2017/745 Classification:	Class I, Rule 1
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.

EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the Regulation (EU) 2017/745.

Name Anne Arndt **Position** PRRC

Signed *Anne Arndt* **Date** 28/01/2026 **Place** Christchurch, NZ

[Anne Arndt \(Feb 2, 2026 13:02:38 GMT+13\)](#)

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 20417:2021	Medical devices. Information supplied by the manufacturer
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
ISO 10093-1	Biological evaluation of medical devices

Appendix II – Product Listing/Schedule

Legacy Catalogue Number	Catalogue Number	Device Name	EMDN Code	GMDM Code
E3q-BI-K	E3q-01-BI-K	Express Kit 3/4 Blue K	Y061203	41575
E3q-BI-L	E3q-01-BI-L	Express Kit 3/4 Blue L	Y061203	41575
E3q-BI-M	E3q-01-BI-M	Express Kit 3/4 Blue M	Y061203	41575
E3q-BI-S	E3q-01-BI-S	Express Kit 3/4 Blue S	Y061203	41575
E3q-BI-XL	E3q-01-BI-XL	Express Kit 3/4 Blue XL	Y061203	41575
E3q-BI-XS	E3q-01-BI-XS	Express Kit 3/4 Blue XS	Y061203	41575
E3q-Re-K	E3q-01-Re-K	Express Kit 3/4 Red K	Y061203	41575
E3q-Re-L	E3q-01-Re-L	Express Kit 3/4 Red L	Y061203	41575
E3q-Re-M	E3q-01-Re-M	Express Kit 3/4 Red M	Y061203	41575
E3q-Re-S	E3q-01-Re-S	Express Kit 3/4 Red S	Y061203	41575
E3q-Re-XL	E3q-01-Re-XL	Express Kit 3/4 Red XL	Y061203	41575
E3q-Re-XS	E3q-01-Re-XS	Express Kit 3/4 Red XS	Y061203	41575
EFl-BI-K	EFl-01-BI-K	Express Kit Full Blue K	Y061203	41575
EFl-BI-L	EFl-01-BI-L	Express Kit Full Blue L	Y061203	41575
EFl-BI-M	EFl-01-BI-M	Express Kit Full Blue M	Y061203	41575
EFl-BI-S	EFl-01-BI-S	Express Kit Full Blue S	Y061203	41575
EFl-BI-XL	EFl-01-BI-XL	Express Kit Full Blue XL	Y061203	41575
EFl-BI-XS	EFl-01-BI-XS	Express Kit Full Blue XS	Y061203	41575
EFl-Re-K	EFl-01-Re-K	Express Kit Full Red K	Y061203	41575
EFl-Re-L	EFl-01-Re-L	Express Kit Full Red L	Y061203	41575
EFl-Re-M	EFl-01-Re-M	Express Kit Full Red M	Y061203	41575
EFl-Re-S	EFl-01-Re-S	Express Kit Full Red S	Y061203	41575
EFl-Re-XL	EFl-01-Re-XL	Express Kit Full Red XL	Y061203	41575
EFl-Re-XS	EFl-01-Re-XS	Express Kit Full Red XS	Y061203	41575

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7	N Belsham	04/10/2024	Updated Signatory and added SRN
8	N Belsham	06/06/2025	Updated to new codes and GMDN added
9	N Belsham	28/01/2026	Legacy Codes listed for reference

DoC - MDR Class I FSI V10

Final Audit Report

2026-02-02

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