

EU DECLARATION OF CONFORMITY

Manufacturer: Blatchford Products Limited
Lister Road
Basingstoke
RG22 4AH
UK

SRN: -

Blatchford Products Limited hereby declare sole responsibility for the product types listed, and, on the basis of their design and manufacture, in the form brought onto the market by Blatchford, that they conform to the applicable requirements of the EU Medical Devices Regulation (EU) 2017/745.

Product Category: **Class I External Prosthetic Medical Devices**

Relevant EU Regulation: Medical Devices Regulation (EU) 2017/745

Basis of Self-Attestation: Conformity is declared based on Article 52 (7) Annex II and Annex III of the Regulation.

Blatchford Products Limited operates a Quality Management System approved to:

- BS EN ISO 9001:2015
- BS EN ISO 13485:2016

Blatchford Products Limited operates a Risk Management System in accordance with:

- BS EN ISO 14971:2019

Authorised Representative: Blatchford Europe GmbH
Fritz-Hornschuch-Str. 9 (3. OG)
D-95326 Kulmbach
Germany

Type	Product Name	Class, Rule	Basic UDI-DI
Foot	Multiflex - SE	Class I, Rule 1	5050649MULTIFLEXSE9H
Foot	Multiflex - Standard	Class I, Rule 1	5050649MULTIFLEXSTD9X
Ankle	Multiflex Ankle	Class I, Rule 1	5050649MULTIFLEXANKLEHN



Signed on behalf of the manufacturer:

Name: S Zahedi Kt OBE FEng BSc. PhD. HonFIMechE CEng RDI
Position/Function: Technical Authority
Place: London UK
Date: 2021 May 26

Product Code	Description	UDI-DI/GTIN	Classification acc. To (EU) 2017/745 Annex VIII
519119	MULTIFLEX EXT. FOOT PROSTHESIS 22 LEFT	5050649012297	Class I, Rule 1
519120	MULTIFLEX EXT. FOOT PROSTHESIS 22 RIGHT	5050649012303	Class I, Rule 1
519121	MULTIFLEX EXT. FOOT PROSTHESIS 23 LEFT	5050649012310	Class I, Rule 1
519122	MULTIFLEX EXT. FOOT PROSTHESIS 23 RIGHT	5050649012327	Class I, Rule 1
519123	MULTIFLEX EXT. FOOT PROSTHESIS 24 LEFT	5050649012334	Class I, Rule 1
519124	MULTIFLEX EXT. FOOT PROSTHESIS 24 RIGHT	5050649012341	Class I, Rule 1
519125	MULTIFLEX EXT. FOOT PROSTHESIS 25 LEFT	5050649012358	Class I, Rule 1
519126	MULTIFLEX EXT. FOOT PROSTHESIS 25 RIGHT	5050649012365	Class I, Rule 1
519127	MULTIFLEX EXT. FOOT PROSTHESIS 26 LEFT	5050649012372	Class I, Rule 1
519128	MULTIFLEX EXT. FOOT PROSTHESIS 26 RIGHT	5050649012389	Class I, Rule 1
519129	MULTIFLEX EXT. FOOT PROSTHESIS 27 LEFT	5050649012396	Class I, Rule 1
519130	MULTIFLEX EXT. FOOT PROSTHESIS 27 RIGHT	5050649012402	Class I, Rule 1
519131	MULTIFLEX EXT. FOOT PROSTHESIS 28 LEFT	5050649012419	Class I, Rule 1
519132	MULTIFLEX EXT. FOOT PROSTHESIS 28 RIGHT	5050649012426	Class I, Rule 1
519133	MULTIFLEX EXT. FOOT PROSTHESIS 29 LEFT	5050649012433	Class I, Rule 1
519134	MULTIFLEX EXT. FOOT PROSTHESIS 29 RIGHT	5050649012440	Class I, Rule 1
519135	MULTIFLEX EXT. FOOT PROSTHESIS 30 LEFT	5050649012457	Class I, Rule 1
519136	MULTIFLEX EXT. FOOT PROSTHESIS 30 RIGHT	5050649012464	Class I, Rule 1
519141	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 22L	5050649012471	Class I, Rule 1
519142	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 22R	5050649012488	Class I, Rule 1
519143	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 23L	5050649012495	Class I, Rule 1
519144	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 23R	5050649012501	Class I, Rule 1
519145	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 24L	5050649012518	Class I, Rule 1
519146	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 24R	5050649012525	Class I, Rule 1
519147	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 25L	5050649012532	Class I, Rule 1
519148	M'FLEX SLIM EXTERNAL FOOT PROSTHESIS 25R	5050649012549	Class I, Rule 1
379342	MULTIFLEX EXT. ANKLE PROSTHESIS 30mm W	5050649011405	Class I, Rule 1
379343	MULTIFLEX EXT. ANKLE PROSTHESIS 30mm O	5050649011412	Class I, Rule 1
379344	MULTIFLEX EXT. ANKLE PROSTHESIS 30mm B	5050649011429	Class I, Rule 1
409241	M/F ANKLE PYL - 60 DEG (W) 30mm 125kg	5050649012075	Class I, Rule 1
409242	M/F ANKLE PYL - 70 DEG (O) 30mm 125kg	5050649012082	Class I, Rule 1
409243	M/F ANKLE PYL - 80 DEG (B) 30mm 125kg	5050649012099	Class I, Rule 1
409353	MULTIFLEX EXT. ANKLE PROSTHESIS PYR W	5050649012150	Class I, Rule 1
409354	MULTIFLEX EXT. ANKLE PROSTHESIS PYR O	5050649012167	Class I, Rule 1
409355	MULTIFLEX EXT. ANKLE PROSTHESIS PYR B	5050649012174	Class I, Rule 1