

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 in Annex 1, 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



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 05 24

Type	Product Name	Class, Rule	Basic UDI-DI
Limb System	Linx	Class I, Rule 1, 13	5050649LINX2G
Knee	Orion3	Class I, Rule 1, 13	5050649ORION3W7
Knee	KX06	Class I, Rule 1	5050649KX06V2NB
Knee	Mercury	Class I, Rule 1	5050649MERCURYB
Foot	Elan	Class I, Rule 1, 13	5050649ELANXG
Foot	ElanIC	Class I, Rule 1, 13	5050649ELANICNM
Foot	Elite2	Class I, Rule 1	5050649ELITE2PX
Foot	EchelonVT	Class I, Rule 1	5050649ECHELONVT6Y
Foot	Echelon	Class I, Rule 1	5050649ECHELONMV
Foot	EchelonER	Class I, Rule 1	5050649ECHELONER59
Foot	EchelonVAC	Class I, Rule 1	5050649ECHELONVACNL
Foot	Epirus	Class I, Rule 1	5050649EPIRUSUH
Foot	Esprit	Class I, Rule 1	5050649ESPRITVZ
Foot	AvalonK2	Class I, Rule 1	5050649AVALONK2Y4
Foot	Mini BladeXT	Class I, Rule 1	5050649MINIBLADEXTJL
Foot	Elite BladeVT	Class I, Rule 1	5050649ELITEBLADEVT9W
Foot	EliteVT	Class I, Rule 1	5050649ELITEVTV4
Foot	Multiflex - SE	Class I, Rule 1	5050649MULTIFLEXSE9H
Foot	Multiflex - Standard	Class I, Rule 1	5050649MULTIFLEXSTD9X
Ankle	Multiflex Ankle	Class I, Rule 1	5050649MULTIFLEXANKLEHN
Ankle	TT Pro	Class I, Rule 1	5050649TTPRO3L
Adapters	Structural Adapters	Class I, Rule 1	5050649STRUCADAP TSA7
Sockets & Accessories	One Shot Socket	Class I, Rule 1	50506491SHOTSKTVE