Blatchford

Blatchford Products Limited
Lister Road
Basingstoke
RG22 4AH
United Kingdom

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
Knee	Orion3	Class I, Rule 1, 13	5050649ORION3W7

Signed on behalf of the manufacturer:

Name: S Zahedi Kt OBE FREng BSc. PhD. HonFIMechE CEng RDI
Position/Function: Technical Authority
Place: London UK
Date: 2021 May 07

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Product Code	Description	UDI-DI/GTIN	Classification acc. To (EU) 2017/745 Annex VIII
ORION3	ORION3 EXTERNAL KNEE PROSTHESIS	5050649091087	Class I, Rule 1, 13

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Registered in England No. 04395856 VAT Reg: GB 787452287
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