

## 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 / Ankle	AvalonK2	Class I, Rule 1	5050649AVALONK2Y4



**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

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Product Code	Description	UDI-DI/GTIN	Classification acc. To (EU) 2017/745 Annex VIII
AV22L	AVALON K2 22L EXTERNAL FOOT PROSTHESIS	5050649025174	Class I, Rule 1
AV22LD	AVALON K2 22L D EXTERNAL FOOT PROSTHESIS	5050649025181	Class I, Rule 1
AV22R	AVALON K2 22R EXTERNAL FOOT PROSTHESIS	5050649025198	Class I, Rule 1
AV22RD	AVALON K2 22R D EXTERNAL FOOT PROSTHESIS	5050649025204	Class I, Rule 1
AV23L	AVALON K2 23L EXTERNAL FOOT PROSTHESIS	5050649025211	Class I, Rule 1
AV23LD	AVALON K2 23L D EXTERNAL FOOT PROSTHESIS	5050649025228	Class I, Rule 1
AV23R	AVALON K2 23R EXTERNAL FOOT PROSTHESIS	5050649025235	Class I, Rule 1
AV23RD	AVALON K2 23R D EXTERNAL FOOT PROSTHESIS	5050649025242	Class I, Rule 1
AV24L	AVALON K2 24L EXTERNAL FOOT PROSTHESIS	5050649025259	Class I, Rule 1
AV24LD	AVALON K2 24L D EXTERNAL FOOT PROSTHESIS	5050649025266	Class I, Rule 1
AV24R	AVALON K2 24R EXTERNAL FOOT PROSTHESIS	5050649025273	Class I, Rule 1
AV24RD	AVALON K2 24R D EXTERNAL FOOT PROSTHESIS	5050649025280	Class I, Rule 1
AV25L	AVALON K2 25L EXTERNAL FOOT PROSTHESIS	5050649025297	Class I, Rule 1
AV25LD	AVALON K2 25L D EXTERNAL FOOT PROSTHESIS	5050649025303	Class I, Rule 1
AV25R	AVALON K2 25R EXTERNAL FOOT PROSTHESIS	5050649025310	Class I, Rule 1
AV25RD	AVALON K2 25R D EXTERNAL FOOT PROSTHESIS	5050649025327	Class I, Rule 1
AV26L	AVALON K2 26L EXTERNAL FOOT PROSTHESIS	5050649025334	Class I, Rule 1
AV26LD	AVALON K2 26L D EXTERNAL FOOT PROSTHESIS	5050649025341	Class I, Rule 1
AV26R	AVALON K2 26R EXTERNAL FOOT PROSTHESIS	5050649025358	Class I, Rule 1
AV26RD	AVALON K2 26R D EXTERNAL FOOT PROSTHESIS	5050649025365	Class I, Rule 1
AV27L	AVALON K2 27L EXTERNAL FOOT PROSTHESIS	5050649025372	Class I, Rule 1
AV27LD	AVALON K2 27L D EXTERNAL FOOT PROSTHESIS	5050649025389	Class I, Rule 1
AV27R	AVALON K2 27R EXTERNAL FOOT PROSTHESIS	5050649025396	Class I, Rule 1
AV27RD	AVALON K2 27R D EXTERNAL FOOT PROSTHESIS	5050649025402	Class I, Rule 1
AV28L	AVALON K2 28L EXTERNAL FOOT PROSTHESIS	5050649025419	Class I, Rule 1
AV28LD	AVALON K2 28L D EXTERNAL FOOT PROSTHESIS	5050649025426	Class I, Rule 1
AV28R	AVALON K2 28R EXTERNAL FOOT PROSTHESIS	5050649025433	Class I, Rule 1
AV28RD	AVALON K2 28R D EXTERNAL FOOT PROSTHESIS	5050649025440	Class I, Rule 1
AV29L	AVALON K2 29L EXTERNAL FOOT PROSTHESIS	5050649025457	Class I, Rule 1
AV29LD	AVALON K2 29L D EXTERNAL FOOT PROSTHESIS	5050649025464	Class I, Rule 1
AV29R	AVALON K2 29R EXTERNAL FOOT PROSTHESIS	5050649025471	Class I, Rule 1
AV29RD	AVALON K2 29R D EXTERNAL FOOT PROSTHESIS	5050649025488	Class I, Rule 1
AV30L	AVALON K2 30L EXTERNAL FOOT PROSTHESIS	5050649025495	Class I, Rule 1
AV30LD	AVALON K2 30L D EXTERNAL FOOT PROSTHESIS	5050649025501	Class I, Rule 1
AV30R	AVALON K2 30R EXTERNAL FOOT PROSTHESIS	5050649025518	Class I, Rule 1
AV30RD	AVALON K2 30R D EXTERNAL FOOT PROSTHESIS	5050649025525	Class I, Rule 1