EU Authorised Representative Mandate

1 Introduction

This mandate documents the designation of Blatchford Europe GmbH as the sole authorised representative of Blatchford Products Limited as required by Medical Devices Regulation (EU) 2017/745.

1.1 Roles

1.1.1 Manufacturer

For the purposes of this mandate the manufacturer and their registered place of business is:

Blatchford Products Limited
Lister Road, Basingstoke, Hampshire, RG22 4AH, UK

1.1.2 EU Authorised Representative

For the purposes of this mandate the EU Authorised Representative and their registered place of business is:

Blatchford Europe GmbH
Am Prime-Parc 4, 65479 Raunheim, Germany

1.2 References

Medical Devices Regulation (EU) 2017/745 Article 11

2 Scope

All devices CE marked by Blatchford Products Limited are covered by this mandate. At the time of writing these devices are outlined below and are all designated Class I. All current Blatchford products can be found at www.blatchford.co.uk.

Integrated Limb

- Linx

Knees

- KX06
- Orion3
- SmartIP
- Mercury
- ESK+
- ESK+ MKL
- S200
- S400
- S500
- Compact SAKL
- AqualimbTF

Feet

- ElanIC
- Elan
- EchelonER
- Echelon
- EchelonVT
- EchelonVAC
- AvalonK2
- Elite2
- EliteVT
- Elite Blade
- Elite BladeVT
- Epirus
- Esprit
- BladeXT
- Javelin
- Multiflex
- Navigator
- Senior
- AqualimbTT
- SuperSACH

Liners

- Silcare Breathe (Cushion)
- Silcare Breathe (Locking)

Children's

- Mini BladeXT
- 4-Bar Knee

Other Products

- Ankles
- Adapters
- Cosmesis
- Sockets, Valves and Locks

3 Mandate

Blatchford Products Limited designates Blatchford Europe GmbH as their single authorised representative in the European Union to act on their behalf in relation to the below specified tasks with regard to their obligations under the Medical Devices Regulation (EU) 2017/745.

Blatchford Products Limited will enable Blatchford Europe GmbH to perform the following tasks:

a) to verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out;
b) to keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Medical Devices Regulation (EU) 2017/745 Article 56, at the disposal of competent authorities for the period referred to in Medical Devices Regulation (EU) 2017/745 Article 10(8);
c) to comply with the registration obligations laid down in Medical Devices Regulation (EU) 2017/745 Article 31 and to verify that the manufacturer has complied with the registration obligations laid down in Medical Devices Regulation (EU) 2017/745 Articles 27 and 29;
d) in response to a request from a competent authority, to provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;
e) to forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and to verify that the competent authority receives the samples or is given access to the device;
f) to cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
g) to immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
h) to terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

Where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Medical Devices Regulation (EU) 2017/745 Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

If the authorised representative terminates its mandate on the grounds referred to in point (h) above shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons.

The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

4 Designation and Acceptance

Designation of Blatchford Europe GmbH as EU Authorised Representative for Blatchford Products Limited:

P.G. 20/4/21

Sign Date

Paul Roberts, Group CEO

Acceptance by Blatchford Europe GmbH as EU Authorised Representative for Blatchford Products Limited:

Marcus T. Walda 20.04.2021

Sign Date

Marcus Walda

Version	Date	Reason	Author
2.0	16 Apr 2021	Section 1.1.2 updated to reflect the new address for Blatchford Europe GmbH.	Julia Pragnell
1.0	09 Dec 2020	New document	Julia Pragnell