

04 December 2020

Memorandum – Indication of the Shelf Life and Useful Life of Blatchford Medical Devices

Dear Sir and Madam/s,

The EU Medical Device Regulation 2017/745 (MDR) becomes fully applicable in May 2021 and Blatchford has been working to ensure that our products meet the MDR and EU Directive 93/42 / EEC for medical devices

Our devices are designed, developed, manufactured and tested in accordance with the ISO13485:2016 standard and structurally tested to ISO 10328 for prostheses in accordance with the MDR requirements. Blatchford operate a continuous improvement culture using information obtained through post-market surveillance to drive this.

Expected service life

Blatchford Products typically have an expected service life of 5 years subject to maintenance requirements (or 6 with specific agreement and adherence to servicing requirements), any use beyond the warranty period is the responsibility of the practitioner and must be supported by a local risk analysis. There are exceptions to this, Blatchford Liners, foot shells and glide socks have a typical expected service life in line with their warranty period. The Child's System should be reviewed regularly in consideration of the growth of the wearer for suitability despite the expected service life.

Devices must have an annual maintenance check as a minimum by suitably qualified personnel. Where specific maintenance activities are documented in the IFU (Instructions for Use) these too must be carried out.

This regular formal evaluation must be used to perform a local risk assessment of product function and condition, this takes into account all applicable factors such as activity level, user weight, product combinations and operating time of the product.

Our Technical Support team are available to provide support for our products, product safety and quality are our number one priority. Please contact our Customer Service team: customer.service@blatchford.co.uk for this or if you have any questions about the implementation of MDR.

Yours faithfully,

Blatchford Products Limited



Amit Bose, Chief Technical Officer



Jason Robson, Group Quality Manager