

# Certificate of Designation



**Client Ref.**            **GBR/2018/10/30**

**Issued To:**            **Mercian Surgical Supply Co Ltd**  
Unit 10 Topaz Business Park  
Topaz Way  
Bromsgrove  
Worcestershire  
B61 0GD  
United Kingdom

**Legal Manufacturer [SRN: Not yet available]**

**Issued By:**            **Advena Limited**  
Tower Business Centre, 2nd Flr, Tower  
Street, Swatar, BKR 4013. Malta.

**EC-REP [SRN: MT-AR-00000234]**

**EU Competent Authority:**    **Malta Medicines Authority (MMA)**  
Sir Temi Zammit Buildings, Malta Life  
Sciences Park, San Gwann SGN 3000  
Malta.  
Tel: +356 2343 9000  
Email: info.medicinesauthority@gov.mt

In accordance with the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Legal Manufacturer.

The devices listed in Appendix A must indicate Advena Ltd as the EU Authorised Representative, and in the following format, as applicable to EU legislation:

<b>EC</b>	<b>REP</b>	<b>Advena Ltd, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta</b>
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Anthony Kirby – Managing Director (Malta)

**Date of Issue:** 27 January 2021

**AR Cover Begins:** 01 December 2020

**AR Cover Ends:** 30 November 2021

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

# Appendix A



Product Details, Names or Trade Names	EU Legislation	Classification	Date of Declaration
Artery Forceps	MDD	Class I	02/12/2020
Bone Punches and Rongeurs	MDD	Class I	02/12/2020
Curettes	MDD	Class I	02/12/2020
Dilators	MDD	Class I	02/12/2020
Dissecting Forceps	MDD	Class I	02/12/2020
Dissectors & Elevators	MDD	Class I	02/12/2020
Hooks & Probes	MDD	Class I	02/12/2020
Mallets, Osteotomes, Chisels & Gouges	MDD	Class I	02/12/2020
Needle Holders	MDD	Class I	02/12/2020
Retractors	MDD	Class I	02/12/2020
Scissors	MDD	Class I	02/12/2020
Vascular Clamps	MDD	Class I	02/12/2020
Wire Cutters and Pliers	MDD	Class I	02/12/2020
Sterile Silicone Digiband Finger & Toe Tourniquet	MDD	Class Is	18/11/2020
Micro Torque Surgical Drill System	MDD	Class IIa	18/11/2020
Sterila Caspar Distraction Screws	MDD	Class IIa	18/11/2020
Sterile Irrigation Tubing	MDD	Class IIa	18/11/2020
Sterile Orthopaedic Surgical Bone Twist Drills	MDD	Class IIa	18/11/2020
Sterile Surgical Burs & Saw Blades	MDD	Class IIa	18/11/2020
Sterile Visibility Background Material	MDD	Class IIa	18/11/2020
Sterile Kirschner Wires, Steinmann & Denham Bone Pins	MDD	Class IIb	18/11/2020