

Certificate of Designation



Client Ref. GBR/2020/03/12

Issued To: Sihong Surgitrac Co Ltd
2 Xihu road,
Sihong industrial park
223900 Jiangsu,
China.

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:



**Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta**

Anthony Kirby – Managing Director (Malta)

Date of Issue: 22 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
Reusable ophthalmic instruments	MDD	Class I	03 rd December 2020
Single use ophthalmic instruments	MDD	Class IIa	03 rd December 2020

