

Certificate BE23/00000270

The management system of

3D-SIDE

Rue André Dumont 5, 1435 Mont-Saint-Guibert, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Manufacture and distribution of non-sterile patient-specific (custom made) additive manufactured synthetic (plastic)

- patient specific surgical guides (bone tumour resection and paediatric instruments)
 - patient specific mould for pre-operative implant manufacturing
 - patient specific bone models
- for the area of bone surgery.

Design, development and manufacture of software, intended for the 3D visualisation and planning of orthopaedic surgeries, CMF surgeries and cranioplasty surgeries.

This certificate is valid from 14 September 2023 until 16 March 2025 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 14 September 2023

Organization certified since 19 September 2016 and first certified by SGS under UKAS since 14 September 2023.

Jonathan M. Hall

Authorised by

Jonathan Hall

Global Head - Certification Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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