



Certificate BE16/819942346

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 17 March 2022 until 16 March 2025 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 19 September 2016

Re certification audit due before 26 January 2025

Authorised by

Pieter Weterings  
Certification Manager  
SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

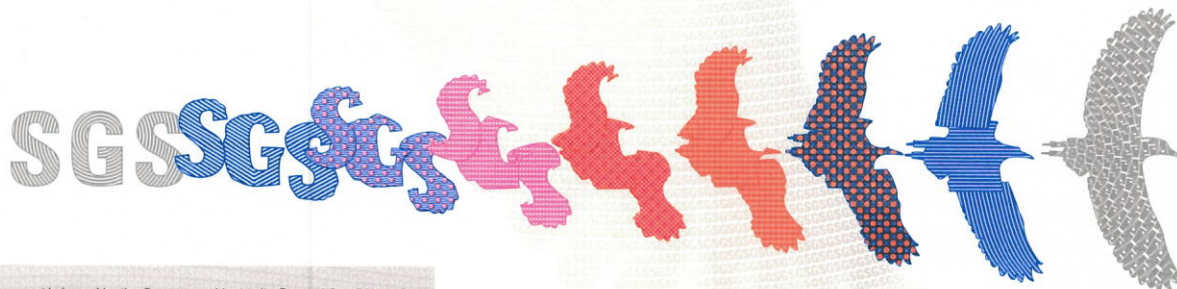
SGS Belgium 13485-2 0308

Page 1 of 1



Accreditation Number

005-QMS  
EN ISO/IEC 17021-1:2015



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.