

Certificate BE12/223574493.00

The management system of

Materialise N.V.

Technologielaan 15
3001 Leuven, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 February 2017 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 7. Certified since 06 March 2012

Multiple certificates have been issued for this scope
The main certificate is numbered BE12/223574493.00

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0614 M2

Page 1 of 2



0005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at 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 <http://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.

Materialise N.V.

ISO 13485:2003 EN ISO 13485:2012



Issue 7

Detailed scope

- Design, development, manufacture and distribution of:**
- medical image processing, simulation and design software,
 - custom made medical models,
 - non-sterile custom made surgical implants and implant solutions
 - non-sterile custom made surgical guides
 - non-sterile cranio-maxillofacial metal implants
- for the area of orthopaedic and cranio-maxillofacial surgery and biomedical engineering and research**

Additional facilities

Materialise Ukraine, LLC
Raisy Okypnoi 8A, 02002 Kyiv, Ukraine

Materialise USA, LLC
44650 Helm Ct, Plymouth, Michigan , United States

Materialise Sdn Bhd
Unit 5-01, Menara OBYU, No. 4, Jalan PJU 8/8A, Damansara Perdana
47820 Petaling Jaya, Selangor , Malaysia

Materialise Colombia S.A.S.
Calle 29, Building nr 41 105 Office nr 401, Edificio S.O.H.O., Medellin, Colombia

Materialise Japan K.K. Advanced Manufacturing
Mori First Bldg. 1F, 2-593 Saiwai-cho, Saiwai-ku, Kawasaki, 212-0011
Kanagawa, Japan

Materialise OBL France
70-86 Avenue de la République, Immeuble Vecteur Sud, Bâtiment A
92320 Chatillon, France



0005

