SGS

Certificate BE08/371019

The management system of

DENTSPLY Implants NV

Research Campus 10
3500 Hasselt, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

**Design, development, manufacture and distribution of
non-sterile surgical guides,
medical image processing, simulation and design software
medical models
for the area of dentistry.
Customer servicing and training to customers.**

Effective Date 17 October 2014 Expiry Date 24 February 2017.
Re certification audit due before 24 January 2017.
Valid subject to satisfactory surveillance audits.
Issue 7. Certified since 14 April 2008.
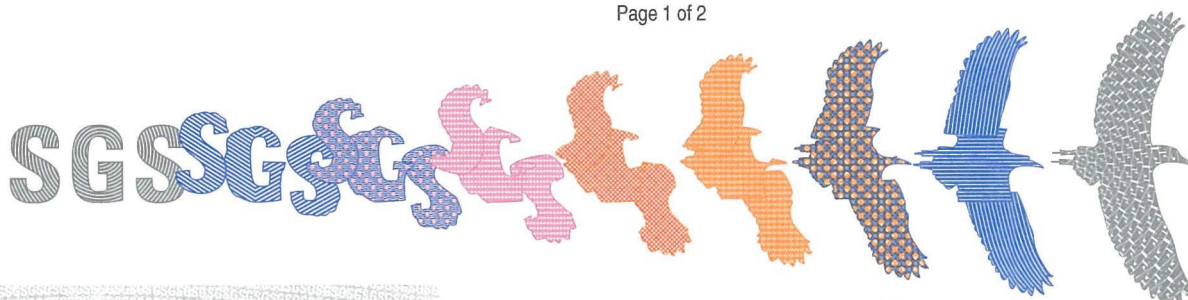
This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by
Jan Saunders – Business Manager

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CMDCAS recognised registrar

SGS 13485 CMDCAS 0311 M2

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DENTSPLY Implants NV

ISO 13485:2003

Issue 7
Detailed scope

Dentsply Implants N.V. (site Hasselt):
Design, development, manufacture and distribution of
non-sterile surgical guides,
medical models
for the area of dentistry.

Dentsply Implants N.V. (site Leuven):
Design, development, manufacture and distribution of
medical image processing, simulation and design software
for the area of dentistry.

Design, development of
non-sterile surgical guides,
medical models
for the area of dentistry.

Customer servicing and training to customers.

Materialise Dental Ukraine LLC:
Design, development and manufacture of
medical image processing, simulation and design software
medical models.

Additional facilities

Dentsply Implants N.V. (site Hasselt)
Research Campus 10
3500 Hasselt, Belgium

Dentsply Implants N.V. (site Leuven)
Grensstraat 1B
3010 Kessel-Lo, Belgium

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

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