



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 148537-2014-CE-ITA-NA 1.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

de Götzen S.r.l

Olgiate Olona, Italy

for design, production and final product inspection/testing of

Cone Beam Computed Tomography System

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 07 April 2015

This Certificate is valid until:

28 January 2019

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Aud Løken Eiklid
Certification Manager

Notified Body No.:
0434

Sholeh Gheissar
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 148537-2014-CE-ITA-NA
Rev. No.: 1.0
Project No.: PRJC-57923-2008-MSL-ITA

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

| Revision | Description | Issue Date |
|------------|--------------------------------------|-------------------|
| | Original certificate | 2014-01-28 |
| 1.0 | Added new clinical indication | 2015-04-07 |

Products covered by this Certificate

| Product Description | Product | Class |
|--|--------------|-------|
| Cone Beam Computed Tomography Scanner, Panoramic and Cephalometric X-ray imaging system used to obtain radiological images of the head including dentomaxillofacial and ENT (ear-nose- throat) areas in diagnostic support | X-MIND trium | IIb |

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

| Site Name | Address |
|------------------|--|
| de Götzen S.r.l. | Via Roma, 45 – 21057 Olgiate Olona - Italy |



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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE