

English version

## Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires (ISO 13485:2016)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016)

This European Standard was approved by CEN on 30 January 2016.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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## CERTIFICATO N° 483DM06

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Si certifica che il  
*this is to certify that*

### Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da  
*implemented by*

**NTC S.r.l.**

Via Luigi Razza, 3 - IT 20124 MILANO (MI)

nella Sede Operativa di  
*Operative Unit*

Via Dei Gracchi, 35 – IT 20146 MILANO (MI)

è conforme alla norma  
*is in compliance with the standard*

**UNI CEI EN ISO 13485-2016 (ISO 13485-2016)**

per i seguenti Processi  
*concerning the following kinds of Processes*

**Gestione della progettazione e della produzione, immissione in commercio a proprio nome di dispositivi medici per uso ginecologico, dispositivi medici per uso oftalmico, dispositivi medici per uso gastrointestinale, dispositivi medici a contatto con pelle lesa, dispositivi medici per la cura di affezioni delle vie aeree superiori e del cavo orale. Commercializzazione di dispositivi medici.**

*Design and manufacturing management, placing on the market of medical devices for gynaecological use, medical devices for ophthalmic use, medical devices for gastrointestinal use, medical devices which come into contact with injured skin, medical devices for the treatment of diseases of the upper airways and of the oral cavity.*

*Marketing of medical devices.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la Certificazione in vigore applicabili.

*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente Certificato, fare riferimento alla lingua italiana

*In case of discrepancies between the languages used in the translation of the content of this certificate, please refer to the Italian language*

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR

A handwritten signature in blue ink, appearing to read 'Roberto Cusolito'.

Dr. Ing. Roberto Cusolito