CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Giesse Technology S.r.l.

Via Maluea 3, Pad. 18

I - 16016 Cogoleto (GE)

has established and applies a quality management system
for the following scope:

Design and manufacturing of medical devices for dental implantology
Production of third parties of medical devices for dental implantology EA 17

Through an Audit, Report No. 0211403, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI EN ISO 9001:2008

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. 39 00 0211403.

This Certificate is valid from 2016-04-20 to 2018-09-14.

The reference date for all the next audits is (day-month): 03-04.

Milan, 2016-04-18. First Certification: 1998-07-17

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

ACCREDIA

SGQ N° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement

TÜVRheinland CERTIFIED

Management System
ISO 9001:2008

www.tuv.com
ID 9105078607

www.tuvitalia.com

TÜVRheinland®

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Giesse Technology S.r.l.

Via Maluea 3, Pad. 18

I - 16016 Cogoleto (GE)

has established and applies a quality management system
for the following scope:

Design and manufacturing of medical devices for dental implantology
Production of third parties of medical devices for dental implantology

Through an Audit, Report No. 0211403, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2012

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. 39 05 0211403.

This Certificate is valid from 2016-04-20 to 2019-04-19.

The reference date for all the next audits is (day-month): 03-04.

Milan, 2016-04-18. First Certification: 1998-07-17

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.

ACCREDIA

SGQ N° 083A SGA N° 052D

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EC Declaration of Conformity

TÜVRheinland®

EC Directive 93/42/EEC Annex II, excluded clause 4

Full Quality Assurance System Medical Devices

Registration No.: HD 60101517 0001

Report No.: 28107631 001

Manufacturer: Giesse Technology S.r.l.
Via Maluea, 3 - Pad. 18
16016 Cogoleto GE - ITALY

Scope: ENDOSSEOUS DENTAL IMPLANTS
PROSTHETIC COMPONENTS AND ACCESSORIES FOR DENTAL IMPLANTS

(See the attachment for models and codes designation)

Date of Expiry: 29/04/2019

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met.
This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity

Notified Body

TÜV Rheinland italia S.r.l. TÜVRheinland Certification Body

Pogliano Milanese (MI) 28/04/2015

B. Tuzza

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)
Accredited by Ministry of Health and by Ministry of Economic Development
with decree of January 9th 2013 (G.U. n. 32 February 7th 2013)

Notified under No. 1936 to the EC Commission

CE The CE marking may be used if all relevant and effective EC Directives are complied with CE

QMF 30.027 rev. 02 del 30/08/2007