

CERTIFICATE

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

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

Mikai S.p.A.

Via P. Gobetti 56R, IT – 16145 Genova

Via Rio Salto 14, IT – 16145 Genova

Via Canestrello 2, IT – 36050 Monteviale (VI)

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

Design, manufacture and placing on the market of medical devices for orthopaedics and traumatology. Distribution of medical devices in the following areas: orthopaedics and traumatology included bone substitutes, neurosurgery, radiology, arthroscopy and for tissue regeneration. Importation of medical devices for arthroscopy.

Through an Audit, Report No. 7993348010MM13, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

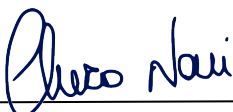
Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0502005**.

This Certificate is valid from 2025/05/01 to 2028/04/30

The reference date for all the next audits is (day-month): 30/04

Milan, 2025/05/01. First Certification: 2002/06/14



The certification responsible: Chiara Novi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of
the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



MS N° 0083

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements.

www.tuvitalia.com



Management
System
EN ISO
13485:2016

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