

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 Gobetti, 56R

IT – 16145 Genova (GE)

Via Canestrello, 2

IT – 36050 Monteviale (VI)

Via Rio Salto, 14R

IT – 16146 Genova (GE)

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

**Design and manufacture of medical devices for orthopaedics and traumatology.
Trade of medical devices in the following sectors: orthopaedics and traumatology,
neurosurgery, radiology and arthroscopy.**

Through an Audit, Report No. 7978791010CN23, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

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 2022-04-29 to 2025-04-30.

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

Milan, 2022-04-29. First Certification: 2002-06-14

The certification responsible: Cesare Gentile
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 or 98/79/EC have been fulfilled.



SGQ N° 083 A

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



Management
System
EN ISO
13485:2016

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