

# 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.

**Sede Legale: Via Gobetti, 56R**

**IT – 16145 Genova (GE)**

**Sede Operativa: Via Canestrello, 2**

**IT – 36050 Monteviale (VI)**

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. 28119549 001, 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 2020-06-29 to 2022-04-30.

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

**Milan, 2020-06-29.** First Certification: 2002-06-14



The certification responsible: Cesare Gentile  
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.



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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