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 guality 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.

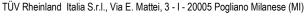
Certificate Registration No. 39 05 0502005.

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





SGQ N° 083 A

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





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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.

