Bureau Veritas Certification

ORTHOKEY ITALIA S.R.L.

Piazza Nazioni Unite, 15 Fraz. Marina di Carrara - 54033 CARRARA (MS) - Italy

Certified sites are listed in the attachment to this certificate

Bureau Veritas Certification Holding SAS - Italy Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

Design, production and placing on the market of medical devices such as navigation systems, including sterile disposable devices, robotic systems, accessories orthopedic digital surgery and digital devices for the assessment of joint kinematics.

Original cycle start date by another certification body:	**12-October-2016**
Expiry date of previous cycle:	**06-May-2025**
Certification / Recertification Audit date:	**21-March-2025**
Certification/Recertification Cycle Start date:	**10-April-2025**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**06-May-2028**

Certificate No. **IT341640** Version: **2** Revision date: **30-May-2025**

Gloria Pocetola

Signed on behalf of BVCH SAS Itay Branch

Certification body address: Viale Monza, 347 - 20126 Milano (MI) Italy
Local office: Viale Monza, 347 - 20126 Milano (MI) Italy

MANAGEMENT SYSTEM CERTIFICATION ACCREDIA 02138

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

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization.
To check the validity of this certificate please double click or scan QR CODE

Bureau Veritas Certification

Attachment to the Certificate of Conformity No. **IT341640**

ORTHOKEY ITALIA S.R.L.

ISO 13485:2016

Certified Sites

Site	Address	Scope
OPERATIVE SITE	Via San Donato, 22 - 50127 FIRENZE (FI) - Italy	Design, production and placing on the market of medical devices such as navigation systems, including sterile disposable devices, robotic systems, accessories orthopedic digital surgery and digital devices for the assessment of joint kinematics.
OPERATIVE UNIT	Piazza Puccini, 26 - 50144 FIRENZE (FI) - Italy	

Certificate No. **IT341640** Version: **2** Revision date: **30-May-2025**

Signed on behalf of BVCH SAS Itay Branch

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