EU Quality Management System Certificate

Issued to

ORTHOKEY ITALIA S.R.L.

Piazza Nazioni Unite,15 – 54033 Carrara (MS) – Italy

Single Registration number: **IT-MF-000026488**

Certified site(s)
Via San Donato, 22 – 50127 Firenze (FI) – Italy
Piazza Giacomo Puccini, 26 – 50144 Firenze (FI) – Italy

Bureau Veritas Italia S.p.A. certifies that the Quality Management System of the above mentioned manufacturer has been audited and it complies with the requirements of

Regulation (EU) 2017/745

(in accordance with annex IX Chapter I, section 2 and 3, and Chapter III)

In relation to the following Medical Device(s):

Model Name(s)	ROBIN Navigation Unit ROBIN Navigation Unit Light
Generic group	Surgical Navigation System
Categoriy	MDA0312: Other active non-implantable devices for surgical use
Risk class	IIa
Basic UDI-DI	805267596Robin2U
Specific conditions or limitations of validity of the certificate	none

Model Name(s) / Device Group:	Orthokey instruments (complete list of models in the Annex to the Certificate)
Generic group	Reusable instruments for orthopedic and trauma surgery - other
Categoriy	MDN1208: Non-implantable, inactive instruments
Risk class	Ir
Basic UDI-DI	805267596SurgicalInstrD9
Specific conditions or limitations of validity of the certificate	The agency's intervention was limited to aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance, functional testing and related instructions for use.

If this certificate covers class III devices or class IIb implantable devices referred to in the second paragraph of Article 52(4), an EU Technical Documentation Assessment Certificate according to Chapter II, Section 4.9 of Annex IX MDR is required before placing them on the market.

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza 375- 20126 Milano ITALY, notified body according to the Regulation (EU) 2017/745 with identification number 1370.

Information on examinations and tests performed regarding relevant CS and harmonized standards, relevant test reports and audit report(s) are in the dossier (FLEX n. 28806979) available on request from medical.device@bureauveritas.com

Bureau Veritas Certification

EU Quality Management System Certificate

Revision History	
Revision	Description
Revision n. IT348354-1 Revision date: 17 Dec. 2025	CER-F-093 28806979_1-21248709278 dated 17 Dec. 2025 : First issue approval

Certificate N°: IT348354 Version: **1** Issue Date: **17 Dec. 2025**

First certificate Issue date: **17 Dec. 2025**
Subject to the continued satisfactory operation of the organization's management system, this certificate expires on: **16 Dec. 2030**

GLORIA FOCETOLA - Local Technical Manager

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Milano, 17/12/2025

Log: C/0772/25/GF/vc

Dichiarazione Certificato IT348354-1:
Declaration Certificate IT348354-1:

Con la presente dichiariamo che l'azienda ORTHOKEY ITALIA S.R.L. è certificata dal nostro Organismo Notificato ai sensi del Regolamento UE 2017/745 (MDR) ed è in possesso del certificato n. IT348354-1, con scadenza il 16 Dicembre 2030.
We hereby declare that ORTHOKEY ITALIA S.R.L. is certified by our Notified Body pursuant to EU Regulation 2017/745 (MDR) and holds Certificate No. IT348354-1, expiring on December 16, 2030.

Le attività di valutazione della conformità relative al dispositivo ROBIN Navigation Unit hanno incluso sia la configurazione come dispositivo di navigazione chirurgica stand-alone sia la configurazione che ne prevede l'utilizzo in combinazione con il prodotto ROBIN Robotic Unit, fabbricato dalla stessa ORTHOKEY ITALIA S.R.L., per l'applicazione in TKA.
The conformity assessment activities for the ROBIN Navigation Unit included both its configuration as a stand-alone surgical navigation device and its configuration for use in combination with the ROBIN Robotic Unit, manufactured by ORTHOKEY ITALIA S.R.L., for TKA applications.

Il prodotto ROBIN Robotic Unit non è coperto del Certificato IT348354-1 in quanto DM di classe I.
The ROBIN Robotic Unit is not covered by Certificate IT348354-1 as it is a Class I MD.

Con l'occasione, vi inviamo i nostri più cordiali saluti.
We take this opportunity to send you our warmest regards.

Gloria Focetola

GLORIA FOCETOLA - Local Technical Manager

Bureau Veritas Italia S.p.A.
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Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine – Francia

Allegato al Certificato IT348354-1:
Attachment to Certificate IT348354-1:

Lista dei dispositive medici coperti dal Certificato UE di Sistema di Gestione della Qualità IT348354-1 rilasciato a ORTHOKEY ITALIA S.R.L..
List of medical devices covered by the EU Quality Management System Certificate IT348354-1 issued to ORTHOKEY ITALIA S.R.L..

Con la presente dichiariamo che l'azienda ORTHOKEY ITALIA S.R.L. è certificata dal nostro Organismo Notificato ai sensi del Regolamento UE 2017/745 (MDR) ed è in possesso del certificato n. IT348354-1, con scadenza il 16 Dicembre 2030.
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I dispositivi medici coperti dal suddetto certificato sono elencati nelle pagine seguenti.:
The medical devices covered by the aforementioned certificate are listed on the following pages:

1. Orthokey Instruments

PRODUCT AREA	REF	SURGICAL INSTRUMENT NAME	MEDICAL DEVICE
ROBIN	GS.N0060	Cutting Guide	Medical Device
ROBIN	GS.N0120	4 in 1 Guide - LNK	Medical Device
ROBIN	GS.N0130	4 in 1 Guide - MTY	Medical Device
ROBIN	GS.N0070	MIS Cutting Guide	Medical Device
ROBIN	GS.N0110	Pin Template	Medical Device
ROBIN	GS.N1110	Pin Template Vers.1	Medical Device
ROBIN	GS.N0030	Knee Pointer	Medical Device
ROBIN	GS.N1030	Knee Tip	Medical Device
ROBIN	GS.N1040	Verification Plan	Medical Device
ROBIN	GS.N1500	Removable Star	Medical Device
ROBIN	GS.N1140	Hip Tip	Medical Device
ROBIN	ANC042359	Resection Verification Tool TKA	Medical Device
ROBIN	UK.N0100	Verification Tool	Medical Device
ROBIN	9061	Femoral distal cutting guide support	Medical Device
ROBIN	2821	Femoral distal cutting guide 1.3 mm Ø3.2 mm	Medical Device
ROBIN	2822	Femoral distal cutting guide 1.3 mm Ø3.4 mm	Medical Device
ROBIN	2823	Femoral distal cutting guide 1.5 mm Ø3.2 mm	Medical Device
ROBIN	2824	Femoral distal cutting guide 1.5 mm Ø3.5 mm	Medical Device
ROBIN	UK.N0200	Cutting block adapter	Medical Device
ROBIN	BD3100	Cutting guide NanoBlock	Medical Device
ROBIN	GS.N0131	4 in1 cutting guide Implantcast	Medical Device
ROBIN	GS.N0133	4 in 1 Guide - Implantcast-5C	Medical Device
ROBIN	20911001	Robot Cutting Block Left 44-40 mm	Medical Device
ROBIN	20911101	Robot Cutting Block Right 44-40 mm	Medical Device
ROBIN	20911002	Robot Cutting Block Left 42-32 mm	Medical Device
ROBIN	20911102	Robot Cutting Block Right 42-32 mm	Medical Device
ROBIN	20911013	Robot Cutting Block Left 40-34 mm	Medical Device
ROBIN	20911113	Robot Cutting Block Right 40-34 mm	Medical Device
PERSEUS	20902401	Extramedullary Jig	Medical Device
PERSEUS	20902402	Extramedullary Jig Vers.1	Medical Device
PERSEUS	20902403	Extramedullary Jig Carbon	Medical Device
PERSEUS	20902501	Perseus Cutting Guide 1.3 mm	Medical Device
PERSEUS	20902502	Perseus Cutting Guide 1.5 mm	Medical Device
PERSEUS	20902503	Perseus Tibial Cutting Guide L PERSEUS 1.3 mm	Medical Device
PERSEUS	20902504	Perseus Tibial Cutting Guide R PERSEUS 1.3 mm	Medical Device
PERSEUS	20902608	Femoral Spacer 8 mm	Medical Device
PERSEUS	20902609	Femoral Spacer 9 mm	Medical Device

PERSEUS	20902610	Femoral Spacer 10 mm	Medical Device
PERSEUS	20902701	Tibial Spacer 0-13 mm	Medical Device
PERSEUS	20904000	Hip Removable Sensor Holder (REF: 20904000), composed by:	Medical Device
	GS.N0021	*Femur Sensor Holder*	*Component*
	20903001B	*Sensor Plate*	*Component*
	20904001B	*base trochanter*	*Component*
PERSEUS	20902301	Verification Plan Perseus	Medical Device
PERSEUS	20903210	Thickness verification Plan 10mm	Medical Device
PERSEUS	20903212	Thickness verification Plan 12mm	Medical Device
PERSEUS	20903214	Thickness verification Plan 14mm	Medical Device
PERSEUS	20903216	Thickness verification Plan 16mm	Medical Device
PERSEUS	20903218	Thickness verification Plan 18mm	Medical Device
PERSEUS	20903220	Thickness verification Plan 20mm	Medical Device
PERSEUS	20903222	Thickness verification Plan 22mm	Medical Device
PERSEUS	20903224	Thickness verification Plan 24mm	Medical Device
PERSEUS	20903226	Thickness verification Plan 26mm	Medical Device
PERSEUS	20903228	Thickness verification Plan 28mm	Medical Device
PERSEUS	300110196	Headed Pin 3.2x20 mm	Medical Device
PERSEUS	300110197	Headed Pin 3.2x35 mm	Medical Device

Questi Dispositivi Medici sono stati verificati durante la verifica della documentazione tecnica e l'audit.
These medical devices were verified during the technical documentation review and audit.

Con l'occasione, vi inviamo i nostri più cordiali saluti.
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Gloria Focetola

GLORIA FOCETOLA - *Local Technical Manager*

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e coordinamento da parte di
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in Neuilly-sur-Seine – Francia