

CERTIFICATO 474-00-01-DM***CERTIFICATE 474-00-01-DM*****ITALCERT S.r.l****Certifica che il*****Certifies that the***

Sistema Completo di Garanzia della Qualità messo in atto
Per la progettazione, la fabbricazione ed il controllo finale di Dispositivi Medici

*Full Quality Assurance System Applied
for the design, manufacture and final inspection of Medical Devices
dal Fabbricante*

by the Manufacturer

TITANIUM ITALICA

nella sede operativa di
in the operational headquarter located in

**#94/195, MAIN PEENYA INDUSTRIAL AREA, 10TH MAIN ROAD,
PHASE 2, BENGALURU-560058, INDIA**

e conforme ai requisiti previsti dalla
complies with the requirements stated in

Direttiva 93/42/CEE- Allegato II (con esclusione del punto 4)***Directive 93/42/EEC- Annex II (excluding point 4)***

ed autorizza lo stesso fabbricante ad apporre la marcatura
and authorises the manufacturer to mark

 **0426**

In accord ai criteri previsti dall'Al. XII della Direttiva 93/42/CEE
Sui dispositivi medici riportati nell'Allegato 1 del presente Certificato
*In compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
The medical devices reported in Annex 1 of this Certificate*



Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Data di rilascio
First Issue Date
2023-09-30

Emissione Corrente
Current Emission
2023-09-29

Data di scadenza
Expire Date
2026-10-26

Il presente Certificato deve essere reso pubblico solo in forma integrale completa dell' Allegato I
This certificate must be published only in integral form accompanied by its Annex 1



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DISPOSITIVI MEDICI IMPLIANTABILI PER ORTOPEDIA ED ACCESSORI *IMPLANTABLE MEDICAL DEVICES FOR ORTHOPEDICS AND ACCESSORIES*

Appendix of EC Design Examination Certificate

Process No. : PP-13468

Certificate No. : 13647GB411200730

Specifications

Femoral Component				
E30.1.00.001	E30.1.00.002	E30.1.00.003	E30.1.00.004	E30.1.00.005
E30.1.00.006	E30.1.00.007	E30.1.00.008	E30.1.00.009	E30.1.00.010
E30.1.00.016	E30.1.00.017	E30.1.00.018	E30.1.00.019	

Tibial Component				
E30.1.00.021	E30.1.00.022	E30.1.00.023	E30.1.00.024	E30.1.00.025
E30.1.00.026	-----	-----	-----	-----

Articular Insert				
E30.1.00.027	E30.1.00.028	E30.1.00.029	E30.1.00.004	E30.1.00.030
E30.1.00.031	E30.1.00.032	E30.1.00.033	E30.1.00.034	E30.1.00.035
E30.1.00.036	E30.1.00.037	E30.1.00.038	E30.1.00.039	E30.1.00.040
E30.1.00.041	E30.1.00.042	E30.1.00.043	E30.1.00.044	E30.1.00.045
E30.1.00.046	E30.1.00.047	E30.1.00.048	E30.1.00.049	E30.1.00.050

Patella Component				
E30.1.00.051	E30.1.00.052	E30.1.00.053	E30.1.00.054	-----

- End of appendix-

Milano, 2023-09-29

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR