



ITALCERT

CERTIFICATE 272-01-01-DM

(in compliance with Annex II of the Directive 93/42/EEC)

ITALCERT S.r.l.

certifies that the

Production Quality Assurance System
applied for the design, manufacture and final inspection of Medical Devices

by the Manufacturer

GRUPPO BIOIMPIANTI S.r.l.

Via Liguria, 28 - 20068 PESCHIERA BORROMEO (MI) - ITALY

in the headquarter located in

Via Liguria, 28 - 20068 PESCHIERA BORROMEO (MI) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

Dr. Ing. Roberto Cusolito
MANAGING DIRECTOR

First Issue Date
2014-12-23

Renewal Date
2019-12-30

Current Emission
2020-04-29

Expire Date
2024-05-26

This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n°272-01-01-DM -DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

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Annex 1 to Certificate 272-01-01-DM

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JOINT PROSTHESES: KNEE PROSTHESIS SYSTEMS and ACCESSORIES - class III -

- **K-MOD** (PRIMARY KNEE ENDOPROSTHESIS)
- **K-MOD REV** (REVISION KNEE ENDOPROSTHESIS)
- **K-MOD PS** (POSTERIOR-STABILIZED KNEE ENDOPROSTHESIS)
- **K-MONO** (FEMOROTIBIAL UNICOMPARTMENTAL ENDOPROSTHESIS)

(code: xxxxxxxx – xxxxxxxxα)

ANCILLARY COMPONENTS FOR KNEE PROSTHESIS - class IIb -

- **K-MOD** (PRIMARY KNEE ENDOPROSTHESIS – ancillary components)
- **K-MOD REV** (REVISION KNEE ENDOPROSTHESIS – ancillary components)
- **K-MONO** (FEMORAL-TIBIAL MONOCOMPARTIMENTAL ENDOPROSTHESIS – ancillary components)

(code: xxxxxxxx – xxxxxxxxα)

Milano, 2020-04-29



Dr. Ing. Roberto Cusolito
MANAGING DIRECTOR