ITALCERT

CERTIFICATO 071-02-03-DM
CERTIFICATE 071-02-03-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
Production Quality Assurance System applied
for the design, manufacture and final inspection of Medical Devices

dal Fabbricante
by the Manufacturer

PERMEDICA S.p.a.
Via Como, 38 – 23807 MERATE (LC) – ITALIA

nella sede operativa di
in the headquarter located in

Via Como 38, - 23807 MERATE (LC) – ITALIA
Via Como 39, - 23807 MERATE (LC) – ITALIA

è 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 authorizes the manufacturer to mark

CE 0426

in accordo ai criteri previsti dall'All. XII della Direttiva 93/42/CEE
sui DM riportati nell'Allegato 1 del presente Certificato
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
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Data di rilascio	Data di rinnovo	Emissione Corrente	Data di scadenza
First Issue Date	*Renewal Date*	*Current Emission*	*Expire Date*
2007-07-02	2017-07-02	2020-07-08	2022-07-01

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

ITALCERT S.r.l. | Organismo Notificato n° 0426 | Viale Sarca, 336 – 20126 Milano (MI)
tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Digitally signed by Chicu Natalia
Date: 2021.06.28 17:25:24 EEST
Reason: MoldSign Signature
Location: Moldova

Allegato 1 al Certificato 071-02-03-DM
Annex 1 to Certificate 071-02-03-DM

PROTESI ARTICOLARI
SISTEMI DI PROTESI DI ANCA e RELATIVI ACCESSORI e STRUMENTARI
ARTICULAR PROSTHESIS
HIP PROSTHESIS SYSTEMS, ACCESSORIES and INSTRUMENTS

STELI FEMORALI PRESS-FIT / *PRESS-FIT FEMORAL STEM*:

Dispositivo / *Device*	**Classe** / *Class*
PBF	III
PBF REVISION	III
PBF/S	III
PBF MODULAR	III
PEGASUS	III
PEGASUS SLIM	III
PEGASUS MODULAR	III
WEDGE	III
WEDGE FULL	III
WEDGE MODULARE / *MODULAR WEDGE*	III
JUMP TITANIUM	III
KONE	III
EXACTA	III
EXACTA S	III
EXACTA SM	III
EXACTA SN	III
EXACTA REVISION	III
EXACTA RS	III
PROMISE S	III
JUST	III
OAK	III
OAK MODULARE / *MODULAR OAK*	III
COLLI MODULARI / *MODULAR NECKS*	III
PM	III
ACCESSORI STELO PM *PM STEM ACCESSORIES*	IIb
SYNTHESIS	III
SL XPORE	III

Allegato 1 al Certificato 071-02-03-DM
Annex 1 to Certificate 071-02-03-DM

STELI FEMORALI CEMENTATI / *CEMENTED FEMORAL STEM*:

Dispositivo / *Device*	**Classe** / *Class*
JUMP PLUS	III
KONE PLUS	III
EXACTA PLUS	III
EXACTA S PLUS	III
EXACTA PLUS REVISION	III
PROMISE PLUS	III
AUTOBLOCCANTE / *SELFLOCKING*	III
SFL	III
CTS	III
WEDGE PLUS	III
PM	III
ACCESSORI STELO PM *PM STEM ACCESSORIES*	IIb
OTTURATORE DIAFISIARIO UNIVERSALE *UNIVERSAL DIAPHYSIARY BLOCK*	IIb

(codici / *codes*: xxxxx – xxxxxV – x.xαxxxβ – x.xαxx-xβ)

STRUMENTARIO CHIRURGICO MOTORIZZABILE PER STELI FEMORALI / *SURGICAL INSTRUMENTS FOR FEMORAL STEMS:*

Dispositivo / *Device*	**Classe** / *Class*
PBF	IIa
PEGASUS	IIa
WEDGE	IIa
JUMP	IIa
AUTOBLOCCANTE / *SELFLOCKING*	IIa
SL XPORE	IIa
CTS	IIa
KONE	IIa
EXACTA	IIa
PROMISE	IIa
OAK	IIa
PM	IIa
SYNTHESIS	IIa

TESTINE FEMORALI / *FEMORAL HEADS* **(Classe III** / *Class III*)

ADATTATORI PER TESTINE FEMORALI / *FEMORAL HEADS ADAPTERS* **(Classe III** / *Class III*)

Allegato 1 al Certificato 071-02-03-DM
Annex 1 to Certificate 071-02-03-DM

TESTE PER HIP RESURFACING / *HIP RESURFACING HEADS* **(Classe III** / *Class III*)

TESTE PER ENDOPROTESI / *ENDOPROTHESIS HEADS* **(Classe III** / *Class III*)

(codici / *codes*: xxxxx)

COTILI PRESS-FIT / *PRESS-FIT ACETABULAR CUP:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP SYSTEM	III
JUMP SYSTEM DISPLASY	III
JUMP SYSTEM COOPER	III
JUMP SYSTEM PEG	III
JUMP SYSTEM TRASER	III
JUMP SYSTEM TRASER REVISION	III
JUMP SYSTEM TRASER REVISION ACCESSORI / *ACCESSORIES*	IIb
JUMP SYSTEM TRASER REVISION MODULAR	III
JUMP SYSTEM UHWMPE INSERTI / *INSERTS*	III
JUMP SYSTEM - VITAL-E e VITAL-XE INSERTI / *INSERTS*	III
JUMP SYSTEM INSERTI PER DOPPIA MOBILITA' / *DUAL MOBILITY INSERTS*	III
JUMP SYSTEM INSERTI CERAMICA / *CERAMIC INSERTS*	III
JUMP SYSTEM RECONSTRUCION	III
JUMP SYSTEM RECONSTRUCION ACCESSORI / *ACCESSORIES*	IIb
PROMISE HR MICROLOY	III
TIFLEX	III
ACORN	III
ACORN INSERTI / *INSERTS*	III
ACORN TRASER BIOLOY	III
JUMP FIT	III
ACCESSORI PER COTILI PRESS-FIT *PRESS-FIT CUP ACCESSORIES*	IIb
JUMP SYSTEM TRASER REVISION MODULAR PLUS	III

Allegato 1 al Certificato 071-02-03-DM
Annex 1 to Certificate 071-02-03-DM

COTILI CEMENTATI / *CEMENTED ACETABULAR CUP:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP SYSTEM CEMENTED	III
ACORN CEMENTED	III
ACORN CEMENTED INSERTI / *INSERTS*	III
ACCESSORI PER COTILI CEMENTATI *CEMENTED CUP ACCESSORIES*	IIb

VITI FISSAGGIO COTILI / *FIXING SCREWS FOR ACETABULAR CUPS* **(Classe IIb** / *Class IIb*)

CUPOLA MOBILE BI-ARTICOLARE / *MOBILE BIARTICULAR CUP* **(Classe IIb** / *Class IIb*)

(codici / *codes:* xxxxx – xxxxxE - xxxxxXE)

STRUMENTARIO MOTORIZZABILE PER COMPONENTI ACETABOLARI / *SURGICAL INSTRUMENTS FOR ACETABULAR CUPS:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP	IIa
JUMP SYSTEM RECONSTRUCION	IIa
JUMP SYSTEM (PRESS FIT)	IIa
TIFLEX	IIa
JUMP FIT	IIa
JUMP SYSTEM CEMENTED	IIa
PROMISE HR MICROLOY	IIa

(codici / *codes*: Sxxxxx/IIa)

Milano, 2020-07-08

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

ITALCERT

CERTIFICATO 071-02-04-DM
CERTIFICATE 071-02-04-DM

ITALCERT S.r.l.

certifica che il
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Sistema Completo di Garanzia della Qualità messo in atto
per la progettazione, la fabbricazione ed il controllo finale di Dispositivi Medici
Production Quality Assurance System applied
for the design, manufacture and final inspection of Medical Devices

dal Fabbricante
by the Manufacturer

PERMEDICA S.p.a.
Via Como, 38 – 23807 MERATE (LC) – ITALIA

nella sede operativa di
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è 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 authorizes the manufacturer to mark

CE 0426

in accordo ai criteri previsti dall'All. XII della Direttiva 93/42/CEE
sui DM riportati nell'Allegato 1 del presente Certificato
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
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Data di rilascio *First Issue Date*	Data di rinnovo *Renewal Date*	Emissione Corrente *Current Emission*	Data di scadenza *Expire Date*
2007-07-02	2017-07-02	2020-12-04	2022-07-01

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Allegato 1 al Certificato 071-02-04-DM
Annex 1 to Certificate 071-02-04-DM

PROTESI ARTICOLARI
SISTEMI DI PROTESI DI ANCA e RELATIVI ACCESSORI e STRUMENTARI
ARTICULAR PROSTHESIS
HIP PROSTHESIS SYSTEMS, ACCESSORIES and INSTRUMENTS

STELI FEMORALI PRESS-FIT / *PRESS-FIT FEMORAL STEM*:

Dispositivo / *Device*	**Classe** / *Class*
PBF	III
PBF REVISION	III
PBF/S	III
PBF MODULAR	III
PEGASUS	III
PEGASUS SLIM	III
PEGASUS MODULAR	III
WEDGE	III
WEDGE FULL	III
WEDGE MODULARE / *MODULAR WEDGE*	III
JUMP TITANIUM	III
KONE	III
EXACTA	III
EXACTA S	III
EXACTA SM	III
EXACTA SN	III
EXACTA REVISION	III
EXACTA RS	III
PROMISE S	III
JUST	III
OAK	III
OAK MODULARE / *MODULAR OAK*	III
COLLI MODULARI / *MODULAR NECKS*	III
PM	III
ACCESSORI STELO PM *PM STEM ACCESSORIES*	IIb
SYNTHESIS	III
SL XPORE	III

Allegato 1 al Certificato 071-02-04-DM
Annex 1 to Certificate 071-02-04-DM

STELI FEMORALI CEMENTATI / *CEMENTED FEMORAL STEM*:

Dispositivo / *Device*	**Classe** / *Class*
JUMP PLUS	III
KONE PLUS	III
EXACTA PLUS	III
EXACTA S PLUS	III
EXACTA PLUS REVISION	III
PROMISE PLUS	III
AUTOBLOCCANTE / *SELFLOCKING*	III
SFL	III
CTS	III
WEDGE PLUS	III
PM	III
ACCESSORI STELO PM *PM STEM ACCESSORIES*	IIb
OTTURATORE DIAFISIARIO UNIVERSALE *UNIVERSAL DIAPHYSIARY BLOCK*	IIb

(codici / *codes*: xxxxx – xxxxxV – x.xαxxxβ – x.xαxx-xβ)

STRUMENTARIO CHIRURGICO MOTORIZZABILE PER STELI FEMORALI E COMPONENTI DI PROVA / *SURGICAL INSTRUMENTS FOR FEMORAL STEMS AND TRIALS:*

Dispositivo / *Device*	**Classe** / *Class*
PBF	IIa
PEGASUS	IIa
WEDGE	IIa
JUMP	IIa
AUTOBLOCCANTE / *SELFLOCKING*	IIa
SL XPORE	IIa
SFL	IIa
CTS	IIa
KONE	IIa
EXACTA	IIa
PROMISE	IIa
OAK	IIa
JUST	IIa
PM	IIa
SYNTHESIS	IIa

Allegato 1 al Certificato 071-02-04-DM
Annex 1 to Certificate 071-02-04-DM

TESTINE FEMORALI / *FEMORAL HEADS* **(Classe III** / *Class III*)

ADATTATORI PER TESTINE FEMORALI / *FEMORAL HEADS ADAPTERS* **(Classe III** / *Class III*)

TESTE PER HIP RESURFACING / *HIP RESURFACING HEADS* **(Classe III** / *Class III*)

TESTE PER ENDOPROTESI / *ENDOPROTHESIS HEADS* **(Classe III** / *Class III*)

(codici / *codes*: xxxxx)

COTILI PRESS-FIT / *PRESS-FIT ACETABULAR CUP:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP SYSTEM	III
JUMP SYSTEM DISPLASY	III
JUMP SYSTEM COOPER	III
JUMP SYSTEM PEG	III
JUMP SYSTEM TRASER	III
JUMP SYSTEM TRASER REVISION	III
JUMP SYSTEM TRASER REVISION ACCESSORI / *ACCESSORIES*	IIb
JUMP SYSTEM TRASER REVISION MODULAR	III
JUMP SYSTEM UHWMPE INSERTI / *INSERTS*	III
JUMP SYSTEM - VITAL-E e VITAL-XE INSERTI / *INSERTS*	III
JUMP SYSTEM INSERTI PER DOPPIA MOBILITA' / *DUAL MOBILITY INSERTS*	III
JUMP SYSTEM INSERTI CERAMICA / *CERAMIC INSERTS*	III
JUMP SYSTEM RECONSTRUCION	III
JUMP SYSTEM RECONSTRUCION ACCESSORI / *ACCESSORIES*	IIb
PROMISE HR MICROLOY	III
TIFLEX	III
ACORN	III
ACORN INSERTI / *INSERTS*	III
ACORN TRASER BIOLOY	III
JUMP FIT	III
ACCESSORI PER COTILI PRESS-FIT *PRESS-FIT CUP ACCESSORIES*	IIb
JUMP SYSTEM TRASER REVISION MODULAR PLUS	III

Allegato 1 al Certificato 071-02-04-DM
Annex 1 to Certificate 071-02-04-DM

COTILI CEMENTATI / *CEMENTED ACETABULAR CUP:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP SYSTEM CEMENTED	III
ACORN CEMENTED	III
ACORN CEMENTED INSERTI / *INSERTS*	III
ACCESSORI PER COTILI CEMENTATI *CEMENTED CUP ACCESSORIES*	IIb

VITI FISSAGGIO COTILI / *FIXING SCREWS FOR ACETABULAR CUPS* **(Classe IIb** / *Class IIb*)

CUPOLA MOBILE BI-ARTICOLARE / *MOBILE BIARTICULAR CUP* **(Classe IIb** / *Class IIb*)

(codici / *codes:* xxxxx – xxxxxE - xxxxxXE)

STRUMENTARIO MOTORIZZABILE PER COMPONENTI ACETABOLARI E COMPONENTI DI PROVA / *SURGICAL INSTRUMENTS FOR ACETABULAR CUPS AND TRIALS:*

Dispositivo / *Device*	**Classe** / *Class*
JUMP	IIa
JUMP SYSTEM RECONSTRUCION	IIa
JUMP SYSTEM (PRESS FIT)	IIa
TIFLEX	IIa
JUMP FIT	IIa
JUMP SYSTEM CEMENTED	IIa
PROMISE HR MICROLOY	IIa

(codici / *codes*: Sxxxxx/IIa)

Milano, 2020-12-04

Dr. Ing. Roberto Cusolito
AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

permedica
ORTHOPAEDICS

DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

Doc. n°: DOCAS-001/A Edizione 16.01

Doc. N°: DOCAS-001/A Edition 16.01

Dispositivi/*Devices*

PROTESI ARTICOLARI E RELATIVI ACCESSORI:
PROTESI D'ANCA – STRUMENTARIO CHIRURGICO MOTORIZZABILE E COMPONENTI DI PROVA PER STELI FEMORALI

(i cui codici e nomi commerciali sono specificati nell'allegato A)

JOINT PROSTHESIS AND RELATED ACCESSORIES:
HIP PROSTHESIS – SURGICAL INSTRUMENTS CONNECTABLE TO AN ACTIVE DEVICE AND TRIAL COMPONENTS FOR FEMORAL STEMS

(codes and commercial name are listed in the attachment A)

Destinazione d'uso/*Intended use*

Strumenti chirurgici da utilizzarsi per l'impianto di sistemi di protesi di anca.

Surgical instruments intended to be used for the implantation of hip joint systems.

Regola di Classificazione/*Classification Rule*

I dispositivi di cui all'oggetto appartengono alla **Classe IIa** in accordo alla Regola 6 dei Criteri di Classificazione dell'Allegato IX della Direttiva 93/42/CEE e successive integrazioni ed emendamenti ed in accordo a quanto riportato nel paragrafo 8.31 "Trial hip prosthesis heads or stems" del "Manual on borderline and classification in the community regulatory framework for medical devices".

*The devices in question are classified as **Class IIa** according to Rule 6 of classification criteria reported in Annex IX of Council Directive 93/42/EEC and subsequent integrations and amendments and according to paragraph 8.31 "Trial hip prosthesis heads or stems" of "Manual on borderline and classification in the community regulatory framework for medical devices".*

Dichiarazione/*Declaration*

Ai sensi dell'allegato II, escluso punto 4, della direttiva 93/42/CEE sui Dispositivi Medici (D.Lgs 24 febbraio 1997, n° 46) e successive integrazioni ed emendamenti, la scrivente **Permedica S.p.A,** con sede legale in via Como, 38 - 23807 Merate (LC) Italia e unità operative in via Como, 38 e 39 -23807 Merate (LC) Italia, Fabbricante dei dispositivi medici oggetto della presente dichiarazione di conformità, dichiara, sotto la propria responsabilità, che:

*According to Council Directive 93/42/EEC (legislation n°46 dated February 24 1997) concerning Medical Devices, Annex II - point 4 excluded, and subsequent integrations and amendments, **Permedica S.p.A.**, having its registered offices in via Como, 38 – 23807 Merate (LC) Italy and production plants in via Como, 38 and 39 – 23807 Merate (LC) Italy, Manufacturer of the medical devices object of the present declaration, declares under its own responsibility that:*

1. i dispositivi di cui all'oggetto soddisfano le disposizioni applicabili della Direttiva 93/42/CEE e successive integrazioni ed emendamenti e, in particolare, i pertinenti requisiti essenziali dell'Allegato I;
   the devices in question meet the applicable provisions of Council Directive 93/42/EEC and subsequent integrations and amendments and, in particular, meet the essential requirements listed in Annex I;
2. i dispositivi di cui all'oggetto sono fabbricati e posti in commercio secondo quanto indicato nel fascicolo tecnico di prodotto FTA-001 nell'ambito dell'applicazione di un Sistema di Gestione per la Qualità aziendale conforme alla norma UNI CEI EN ISO 13485:2016 (Certificato n. **375DM06** rilasciato dall'Ente Notificato ITALCERT viale Sarca, 336 – 20126 Milano – Italia).
   *the devices in question are manufactured and marketed according to information reported in the product technical file FTA-001 within the scope of a Quality Management System compliant to UNI CEI EN ISO 13485:2016 requirements (Certificate n. **375DM06** released by the Notified Body ITALCERT viale Sarca, 336 – 20126 Milan – Italy).*
3. i dispositivi di cui all'oggetto vengono forniti allo stato **NON STERILE.**
   *the devices in question are supplied in the **NON-STERILE** condition.*

permedica spa - *via Como 38, 23807 Merate (Lc) – Italy ; Ph. +39 039 95.14.811 - Fax +39 039 99.03.078*
info@permedica.com – www.permedica.com ; P.I. : IT 01975020130 – C.F./CCIAA LC : 07747160153 – R.E.A. 231575

permedica
ORTHOPAEDICS

DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

Doc. n°: DOCAS-001/A Edizione 16.01

Doc. N°: DOCAS-001/A Edition 16.01

Allegati/*Attachments*:

- Allegato A - Elenco codici prodotto (totale pagine 1).
  Attachment A - List of product codes (total n° of pages 1).

Certificati/*Certificates*

Questa dichiarazione è supportata dai Certificati emessi dall'Ente Notificato:
This declaration is supported by the Certificates issued by the Notified Body:

ITALCERT n° identificazione/*identification n°*: 0426

Viale Sarca, 336 – 20126 MILANO

Italia/*Italy*

Certificato CE n°/*EC Certificate n°*: **071-02-04-DM**	Data di 1° rilascio/*1st issue date*: 2007-07-02 Data di scadenza/*expiry date*: 2022-07-01

La presente dichiarazione di conformità è conservata per 10 anni dall'immissione sul mercato dell'ultimo dispositivo
The present declaration of conformity is kept available for 10 years after the last device has been placed on the market.

Data preparazione/*Preparation date*:	20/11/2020	Approvata da/*Approved by* Marco Perego (Amministratore Unico/*Sole Administrator*):
Data validità/*Effective date*:	09/12/2020	Merate, 09/12/2020

permedica spa - *via Como 38, 23807 Merate (Lc) – Italy ; Ph. +39 039 95.14.811 - Fax +39 039 99.03.078*
info@permedica.com – www.permedica.com ; P.I. : IT 01975020130 – C.F./CCIAA LC : 07747160153 – R.E.A. 231575

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Attachment A to DoC n° DOCAS-001/A Edition 16.01

List of product codes

This document is a true extraction from the list of product codes attached to the original copy of the DoC.

Ref.	Description	Class
S11650	EXACTA Stem INSTRUMENTS SET - Mark S Series	IIa

permedica spa - *via Como 38, 23807 Merate (Lc) – Italy ; Ph. +39 039 95.14.811 - Fax +39 039 99.03.078*
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ORTHOPAEDICS

CE DECLARATION OF CONFORMITY

18th Edition of 30/08/2018 -Version of 09/07/2020

According to Appendix II of the Directive 93/42/CEE Regarding Medical Devices (D.Lgs February 24 1997, n. 46) and successive amendments and integrations

The undersigned **permedica spa**, with legal offices in Via Como, 38 - 23807 Merate (LC) Italy and operative units in Via Como, 38 and 39 – 23807 Merate (LC), manufacturer of medical devices called:

JOINT PROSTHESES AND RELATED ACCESSORIES
HIP PROSTHESES: ACETABULAR COMPONENTS

(whose codes and trade names are specified in the appendix)

declares, under its own responsibility, that:

1. the devices in question meet all the applicable dispositions of Directive 93/42/EEC and successive amendments and integrations on Medical Devices, and in particular the essential requirements of Appendix I;
2. the devices in question meet the requisites of the attached standards;
3. the devices in question are to be considered as belonging to **Class IIb** in compliance with the Rule n. 8 of Appendix IX of Directive 93/42/EEC and successive amendments and integrations of Medical Devices or to **Class III** in compliance with Directive 2005/50/CE relative to the reclassification of hip, knee and shoulder joint prostheses, which modifies classification criteria of Appendix IX of Directive 93/42/EEC (in the appendix the product class is specified).
4. the devices in question are supplied in **STERILE** packs;
5. undertakes to maintain the technical product dossier, as well as the design, production and control registrations (batch records) for a period of at least fifteen years from the last date of manufacture of the last product batch, and to make the same available to the Notified Body and Competent National Authority;
6. the devices in question are manufactured and placed on the market according to the product technical dossier located within the company quality management system in compliance with standards UNI CEI EN ISO 13485:2016 (Certificate n. **375DM06** released by Certification Body ITALCERT, viale Sarca, 336 – 20126 Milan – Italy).
7. has instituted and maintains a suitable procedure to guarantee after-sales surveillance required by Directive 93/42/EEC and successive amendments and integrations in accordance with European guide MEDDEV 2.12-1.

Notified Body: **ITALCERT** (code 0426) - Viale Sarca, 336 - 20126 MILANO - Italy
Certificate n. ° 071-02-03-DM
Date of first release: 2007-07-02 Expiration date: 2022-07-01.

This Declaration of Conformity has a validity of 15 years.

Merate, 09/07/2020 Marco Perego (General Manager): _____

Appendices:

- Product codes list (total pages n. 4)
- Reference standards list (total pages n. 2)

permedica
ORTHOPAEDICS

Attached to the CE DECLARATION OF CONFORMITY Acetabular Components - Hip System
Date: 09/07/2020

Code	Description	Class
35342	*JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 42mm - GREEN (on request)*	III
35345	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 44mm - BLACK	III
35347	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 46mm - BLACK	III
35349	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 48mm - YELLOW	III
35350	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 50mm - YELLOW	III
35353	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 52mm - GREY	III
35355	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 54mm - GREY	III
35356	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 56mm - BLUE	III
35358	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 58mm - BLUE	III
35360	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 60mm - BLUE	III
35362	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 62mm - RED	III
35364	JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 64mm - RED	III
35366	*JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 66mm - RED (on request)*	III
35368	*JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 68mm - RED (on request)*	III
35370	*JUMP SYSTEM CUP -W/holes HaX-Pore - Ø 70mm - RED (on request)*	III
35103	JUMP SYSTEM: Polar Plug (M10)	IIb
36301XE	JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° - BLACK	III
36302XE	JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - BLACK	III
36363XE	JUMP SYSTEM VITAL-XE INSERT- Ø 28mm - 10° - BLACK	III
36305XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° - YELLOW (on request)*	III
36311XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° - GREY (on request)*	III
36321XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° - WHITE (on request)*	III
36307XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° - BLUE (on request)*	III
36309XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 0° -RED (on request)*	III
36306XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - YELLOW (on request)*	III
36312XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - GREY (on request)*	III
36323XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - WHITE (on request)*	III
36308XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - BLUE (on request)*	III
36310XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 28mm - 20° - RED (on request)*	III
36313XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 0° - YELLOW	III
36319XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 0° - GREY	III
36315XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 0° - BLUE (on request)*	III
36317XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 0° - RED (on request)*	III
36340XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 0° - WHITE (on request)*	III
36314XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 20° - YELLOW	III
36320XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 20° - GREY	III
36316XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 20° - BLUE (on request)*	III

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36318XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 20° - RED (on request)*	III
36342XE	*JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 20° - WHITE (on request)*	III
36368XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 10° - YELLOW	III
36369XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 10° - GREY	III
36370XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 10° - BLUE	III
36371XE	JUMP SYSTEM VITAL-XE INSERT - Ø 32mm - 10° - RED	III
36325XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 0° - BLUE	III
36327XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 0° - RED	III
36343XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 0° - WHITE	III
36380XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 0° - GREY	III
36326XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 20° - BLUE	III
36328XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 20° - RED	III
36345XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 20° - WHITE	III
36381XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 20° - GREY	III
36382XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 10° - GREY	III
36329XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 10° - BLUE	III
36330XE	JUMP SYSTEM VITAL-XE INSERT - Ø 36mm - 10° - RED	III
36346XE	JUMP SYSTEM VITAL-XE INSERT - Ø 40mm - 0° - BLUE	III
36348XE	JUMP SYSTEM VITAL-XE INSERT - Ø 40mm - 0° - RED	III
36347XE	JUMP SYSTEM VITAL-XE INSERT - Ø 40mm - 20° - BLUE	III
36349XE	JUMP SYSTEM VITAL-XE INSERT - Ø 40mm - 20° - RED	III
36720	JUMP FIX. SCREW - Flat head Ø 6,5x20mm	IIb
36725	JUMP FIX. SCREW - Flat head Ø 6,5x25mm	IIb
36730	JUMP FIX. SCREW - Flat head Ø 6,5x30mm	IIb
36735	JUMP FIX. SCREW - Flat head Ø 6,5x35mm	IIb
36740	JUMP FIX. SCREW - Flat head Ø 6,5x40mm	IIb
36745	JUMP FIX. SCREW - Flat head Ø 6,5x45mm	IIb
36750	JUMP FIX. SCREW - Flat head Ø 6,5x50mm	IIb
36760	JUMP FIX. SCREW - Flat head Ø 6,5x60mm	IIb
26742	BI-ARTICULAR CUP PM734 - Ø 28x42mm	III
26743	BI-ARTICULAR CUP PM734 - Ø 28x43mm	III
26744	BI-ARTICULAR CUP PM734 - Ø 28x44mm	III
26745	BI-ARTICULAR CUP PM734 - Ø 28x45mm	III
26746	BI-ARTICULAR CUP PM734 - Ø 28x46mm	III
26747	BI-ARTICULAR CUP PM734 - Ø 28x47mm	III
26748	BI-ARTICULAR CUP PM734 - Ø 28x48mm	III
26749	BI-ARTICULAR CUP PM734 - Ø 28x49mm	III
26750	BI-ARTICULAR CUP PM734 - Ø 28x50mm	III
26751	BI-ARTICULAR CUP PM734 - Ø 28x51mm	III
26752	BI-ARTICULAR CUP PM734 - Ø 28x52mm	III
26753	BI-ARTICULAR CUP PM734 - Ø 28x53mm	III
26754	BI-ARTICULAR CUP PM734 - Ø 28x54mm	III

26755	BI-ARTICULAR CUP PM734 - Ø 28x55mm	III
26756	BI-ARTICULAR CUP PM734 - Ø 28x56mm	III
26757	BI-ARTICULAR CUP PM734 - Ø 28x57mm	III
26758	BI-ARTICULAR CUP PM734 - Ø 28x58mm	III
26759	BI-ARTICULAR CUP PM734 - Ø 28x59mm	III
26760	BI-ARTICULAR CUP PM734 - Ø 28x60mm	III
25939	MODULAR BI-ARTICULAR CUP PM734 - Ø 39mm	III
25940	MODULAR BI-ARTICULAR CUP PM734 - Ø 40mm	III
25941	MODULAR BI-ARTICULAR CUP PM734 - Ø 41mm	III
25942	MODULAR BI-ARTICULAR CUP PM734 - Ø 42mm	III
25943	MODULAR BI-ARTICULAR CUP PM734 - Ø 43mm	III
25944	MODULAR BI-ARTICULAR CUP PM734 - Ø 44mm	III
25945	MODULAR BI-ARTICULAR CUP PM734 - Ø 45mm	III
25946	MODULAR BI-ARTICULAR CUP PM734 - Ø 46mm	III
25947	MODULAR BI-ARTICULAR CUP PM734 - Ø 47mm	III
25948	MODULAR BI-ARTICULAR CUP PM734 - Ø 48mm	III
25949	MODULAR BI-ARTICULAR CUP PM734 - Ø 49mm	III
25950	MODULAR BI-ARTICULAR CUP PM734 - Ø 50mm	III
25951	MODULAR BI-ARTICULAR CUP PM734 - Ø 51mm	III
25952	MODULAR BI-ARTICULAR CUP PM734 - Ø 52mm	III
25953	MODULAR BI-ARTICULAR CUP PM734 - Ø 53mm	III
25954	MODULAR BI-ARTICULAR CUP PM734 - Ø 54mm	III
25955	MODULAR BI-ARTICULAR CUP PM734 - Ø 55mm	III
25956	MODULAR BI-ARTICULAR CUP PM734 - Ø 56mm	III
25957	MODULAR BI-ARTICULAR CUP PM734 - Ø 57mm	III
25958	MODULAR BI-ARTICULAR CUP PM734 - Ø 58mm	III
25959	MODULAR BI-ARTICULAR CUP PM734 - Ø 59mm	III
25960	MODULAR BI-ARTICULAR CUP PM734 - Ø 60mm	III
26971	BI-ARTICULAR CUP MODULAR: Insert Ø 28 Size 39/42 - GREEN	III
26972	BI-ARTICULAR CUP MODULAR: Insert Ø 28 Size 43/45 - YELLOW	III
26973	BI-ARTICULAR CUP MODULAR: Insert Ø 28 Size 46/52 - BLUE	III
26974	BI-ARTICULAR CUP MODULAR: Insert Ø 28 Size 53/60 - RED	III
38638	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 38mm	III
38640	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 40mm	III
38642	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 42mm	III
38644	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 44mm	III
38646	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 46mm	III
38648	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 48mm	III
38650	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 50mm	III
38652	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 52mm	III
38654	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 54mm	III
38656	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 56mm	III

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38658	ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 58mm	III
38660	*ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 60mm*	III
38662	*ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 62mm*	III
38664	*ACORN: DUAL MOBILITY Acetabular Cup Cemented - Ø 64mm*	III
38338	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 38mm	III
38340	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 40mm	III
38342	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 42mm	III
38344	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 44mm	III
38346	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 46mm	III
38348	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 48mm	III
38350	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 50mm	III
38352	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 52mm	III
38354	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 54mm	III
38356	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 56mm	III
38358	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 58mm	III
38360	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 60mm	III
38362	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 62mm	III
38364	ACORN Primary: DUAL MOBILITY Acetabular Cup HaX-Pore - Ø 64mm	III
38838	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x38mm	III
38840	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x40mm	III
38842	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x42mm	III
38844	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x44mm - SYSTEM BLACK	III
38946	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x46mm - SYSTEM YELLOW	III
38948	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x48mm - SYSTEM GREY	III
38950	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x50mm	III
38952	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x52mm - SYSTEM BLUE	III
38954	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x54mm - SYSTEM RED	III
38956	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x56mm	III
38958	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x58mm	III
38960	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x60mm	III
38962	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x62mm	III
38964	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 22x64mm	III
38846	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x46mm - SYSTEM YELLOW	III
38848	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x48mm - SYSTEM GREY	III
38850	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x50mm	III
38852	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x52mm - SYSTEM BLUE	III
38854	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x54mm - SYSTEM RED	III
38856	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x56mm	III
38858	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x58mm	III
38860	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x60mm	III
38862	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x62mm	III
38864	ACORN: DUAL MOBILITY UHMWPE Insert - Ø 28x64mm	III

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Allegato della Dichiarazione di Conformità:
Attached to Declaration of Conformity:
Protesi Articolari e Relativi Accessori - Protesi d'Anca: Componenti Acetabolari
Joint Prostheses and Related Accessories – Hip Prostheses: Acetabular Components

Elenco norme di riferimento / Standard List Preparato il 28/02/2020 – Emesso il 09/07/2019 Prepared on 28/02/2020 – Released on 09/07/2019		
Doc. n°	***Title***	***Ed. / Date***
UNI CEI EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	Mar. 2016
UNI EN ISO 14630	Non-active surgical implants — General requirements	Gen. 2013
UNI EN ISO 21534	Non-active surgical implants – Joint replacement implants- Particular requirements	Mag. 2009
UNI EN ISO 21535	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants	Mar. 2017
ISO 7206/1	Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions	01/04/08
ISO 7206/2	Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials	24/03/11
UNI 9768 (Withdrawn without substitution in feb. 2009)	Impianti chirurgici. Viti metalliche per osso. Requisiti meccanici e metodi di prova	Nov. 1990
UNI 9774 (Withdrawn without substitution in feb. 2009)	Impianti chirurgici. Viti metalliche per osso. Dimensioni	Nov. 1994
UNI CEI EN ISO 14971	Medical devices – Application of risk management to medical devices	Ott. 2012
ISO 5832/1	Implants for surgery Metallic materials Part 1: Wrought stainless steel	15/07/16
ISO 5832/2	Implants for surgery. Metallic materials. Part 2: Unalloyed titanium	15/07/99
ISO 5832/3	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6 – aluminium 4 – vanadium alloy	15/10/16

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ISO 5832/4	Implants for surgery. Metallic materials. Part 4: cobalt- chromium-molybdenum casting alloy	15/09/14
ISO 5832/9	Implants for surgery. Metallic materials. Part 9: Wrought high nitrogen stainless steel	15/06/07
ISO 5832/12	Implants for surgery. Metallic materials. Part 12: Wrought cobalt-cromium-molybdenum alloy	01/05/07
ISO 5834/1	Implants for surgery Ultra high molecular weight polyethylene Part 1: powder form	Feb. 2019
ISO 5834/2	Implants for surgery Ultra high molecular weight polyethylene Part 2: Moulded form	Feb. 2019
ISO 13779/2	Implants for surgery. Hydroxyapatite. Coatings of hydroxyapatite	01/10/08
ASTM F 2695-12	Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications	Mag. 2012
ASTM F 2924-14	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion	Feb. 2014
ASTM F 3001-14	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion	Feb. 2014
ISO 6474-1	Implants for surgery -- Ceramic materials - Part 1: Ceramic materials based on high purity alumina	28/01/10
ISO 6474-2	Implants for surgery. Ceramic materials - Part 2 - Composite materials based on a high purity alumina matrix with zirconia reinforcement	15/04/12

UNI EN ISO 10993-1 (previous EN 30993-1: 1994)	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Apr. 2010

UNI CEI EN ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Mar. 2017
UNI CEI EN 1041	Information supplied by the manufacturer of medical devices	Dec. 2013

UNI EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Nov. 2017

UNI EN ISO 14644-1	Cleanrooms and associated controlled environments Part 1: Classification or air cleanliness by particle concentration	Feb. 2016

UNI EN ISO 14644-2	Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness concentration	Feb. 2016

EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical device	Ott. 2001
UNI EN ISO 11137-1	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Nov. 2015
UNI EN ISO 11137-2	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose	Nov. 2015
ISO 11135	Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices	15/07/14
ISO 10993-7	Biological evaluation of medical devices – Ethylene oxide sterilization residuals	15/10/08

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CE DECLARATION OF CONFORMITY

17th Edition of 30/08/2018 -Version of 09/07/2020

According to Appendix II of the Directive 93/42/CEE Regarding Medical Devices (D.Lgs February 24 1997, n. 46)

The undersigned **permedica spa,** with legal offices in Via Como, 38 - 23807 Merate (LC) Italy and operative units in Via Como, 38 and 39 – 23807 Merate (LC), manufacturer of medical devices called:

JOINT PROSTHESES AND RELATED ACCESSORIES
HIP PROSTHESES: ARTICULAR HEADS

(whose codes and trade names are specified in the appendix)

declares, under its own responsibility, that:

1. the devices in question meet all the applicable dispositions of Directive 93/42/EEC and successive amendments and integrations on Medical Devices, and in particular the essential requirements of Appendix I;
2. the devices in question meet the requisites of the attached standards;
3. the devices in question are to be considered as belonging to **Class III** in compliance with Directive 2005/50/CE relative to reclassification of hip, knee and shoulder joint prostheses, which modifies classification criteria of Appendix IX of Directive 93/42/EEC;
4. the devices in question are supplied in **STERILE** packages;
5. undertakes to preserve the technical product dossier, as well as the design, production and control registrations (batch records) for a period of at least fifteen years from the last date of manufacture of the last product batch, and to make the same available to the Notified Body and Competent National Authority;
6. the devices in question are manufactured and placed on the market according to the product technical dossier located within the company quality management system in appliance with standards UNI CEI EN ISO 13485:2016 (Certificate n. **375DM06** released by Certification Body ITALCERT, viale Sarca, 336 – 20126 Milan – Italy).
7. has instituted and maintains a suitable procedure to guarantee after-sales surveillance required by Directive 93/42/EEC and successive amendments and integrations in accordance with European guide MEDDEV 2.12-1.

Notified Body: **ITALCERT** (code 0426) Viale Sarca, 336 - 20126 MILANO -Italy
Certificate n.: **071-02-03-DM**

Date of first release: 2007-07-02 Expiration date: 2022-07-01.

The present declaration of conformity is valid for 15 years.

Merate, 09/07/2020 Marco Perego (General Manager): _____

Appendices:

- Products code list (total pages n. 2)
- Standards reference list (total pages n. 2)

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Attached to the CE DECLARATION OF CONFORMITY Articular Heads - Hip System
Date: 09/07/2020

Code	Description	Class
20321	BALL HEAD, CR-CO - 12/14 - Ø 22mm - SHORT neck (on request)	III
20322	BALL HEAD, CR-CO - 12/14 - Ø 22mm - MEDIUM neck (on request)	III
20323	BALL HEAD, CR-CO - 12/14 - Ø 22mm - LONG neck (on request)	III
20381	BALL HEAD, CR-CO - 12/14 - Ø 28mm - SHORT neck	III
20382	BALL HEAD, CR-CO - 12/14 - Ø 28mm - MEDIUM neck	III
20383	BALL HEAD, CR-CO - 12/14 - Ø 28mm - LONG neck	III
20384	BALL HEAD, CR-CO - 12/14 - Ø 28mm - XL neck	III
20331	BALL HEAD, CR-CO - 12/14 - Ø 32mm - SHORT neck	III
20332	BALL HEAD, CR-CO - 12/14 - Ø 32mm - MEDIUM neck	III
20333	BALL HEAD, CR-CO - 12/14 - Ø 32mm - LONG neck	III
20334	BALL HEAD, CR-CO - 12/14 - Ø 32mm - XL neck	III
20391	BALL HEAD, CR-CO - 12/14 - Ø 36mm - SHORT neck	III
20392	BALL HEAD, CR-CO - 12/14 - Ø 36mm - MEDIUM neck	III
20393	BALL HEAD, CR-CO - 12/14 - Ø 36mm - LONG neck	III
20394	BALL HEAD, CR-CO - 12/14 - Ø 36mm - XL neck	III
20221	BALL HEAD, PM734 - 12/14 - Ø 22mm - SHORT neck	III
20222	BALL HEAD, PM734 - 12/14 - Ø 22mm - MEDIUM neck	III
20223	BALL HEAD, PM734 - 12/14 - Ø 22mm - LONG neck	III
20281	BALL HEAD, PM734 - 12/14 - Ø 28mm - SHORT neck	III
20282	BALL HEAD, PM734 - 12/14 - Ø 28mm - MEDIUM neck	III
20283	BALL HEAD, PM734 - 12/14 - Ø 28mm - LONG neck	III
20231	BALL HEAD, PM734 - 12/14 - Ø 32mm - SHORT neck	III
20232	BALL HEAD, PM734 - 12/14 - Ø 32mm - MEDIUM neck	III
20233	BALL HEAD, PM734 - 12/14 - Ø 32mm - LONG neck	III
20291	BALL HEAD, PM734 - 12/14 - Ø 36mm - SHORT neck	III
20292	BALL HEAD, PM734 - 12/14 - Ø 36mm - MEDIUM neck	III
20293	BALL HEAD, PM734 - 12/14 - Ø 36mm - LONG neck	III
20284	BALL HEAD, PM734 - 12/14 - Ø 28mm - XL neck	III
20234	BALL HEAD, PM734 - 12/14 - Ø 32mm - XL neck	III
20294	BALL HEAD, PM734 - 12/14 - Ø 36mm - XL neck	III
20587	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 28mm - SHORT neck	III
20588	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 28mm - MEDIUM neck	III
20589	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 28mm - LONG neck	III
20537	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 32mm - SHORT neck	III
20538	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 32mm - MEDIUM neck	III
20539	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 32mm - LONG neck	III
20540	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 32mm - X-LONG neck	III
20567	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 36mm - SHORT neck	III
20568	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 36mm - MEDIUM neck	III
20569	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 36mm - LONG neck	III
20570	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 36mm - X-LONG neck	III

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20547	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 40mm - SHORT neck	III
20548	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 40mm - MEDIUM neck	III
20549	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 40mm - LONG neck	III
20550	BALL HEAD, BIOLOX DELTA - 12/14 - Ø 40mm - X-LONG neck	III

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Allegato della Dichiarazione di Conformità:
Attached to Declaration of Conformity:
Protesi Articolari e Relativi Accessori - Protesi d'Anca: Teste Femorali
Joint Prostheses and Related Accessories – Hip Prostheses: Femoral Heads

Elenco norme di riferimento / Standard List Preparato il 09/07/2019 – Emesso il 09/07/2020 Prepared on 09/07/2019 – Released on 09/07/2020		
Doc. n°	***Title***	***Ed. / Date***
UNI CEI EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	Mar. 2016
UNI EN ISO 14630	Non-active surgical implants — General requirements	Gen. 2013
UNI EN ISO 21534	Non-active surgical implants – Joint replacement implants- Particular requirements	Mag. 2009
UNI EN ISO 21535	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants	Mar. 2017
ISO 7206/1	Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions	01/04/08
ISO 7206/2	Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials	24/03/11
UNI CEI EN ISO 14971	Medical devices – Application of risk management to medical devices	Ott. 2012
ISO 5832/1	Implants for surgery Metallic materials Part 1: Wrought stainless steel	15/07/16
ISO 5832/3	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6 – aluminium 4 – vanadium alloy	15/10/16
ISO 5832/4	Implants for surgery. Metallic materials. Part 4: cobalt- chromium-molybdenum casting alloy	15/09/14
ISO 5832/9	Implants for surgery. Metallic materials. Part 9: Wrought high nitrogen stainless steel	15/06/07
ISO 5832/12	Implants for surgery. Metallic materials. Part 12: Wrought cobalt-cromium-molybdenum alloy	01/05/07
ISO 6474-1	Implants for surgery -- Ceramic materials - Part 1: Ceramic materials based on high purity alumina	28/01/10
ISO 6474-2	Implants for surgery. Ceramic materials - Part 2 - Composite materials based on a high purity alumina matrix with zirconia reinforcement	15/04/12

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UNI EN ISO 10993-1 (previous EN 30993-1: 1994)	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Apr. 2010

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UNI EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Nov. 2017

UNI EN ISO 14644-1	Cleanrooms and associated controlled environments Part 1: Classification or air cleanliness by particle concentration	Feb. 2016
UNI EN ISO 14644-2	Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness concentration	Feb. 2016

EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical device	Ott. 2001
UNI EN ISO 11137-1	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Nov. 2015
UNI EN ISO 11137-2	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose	Nov. 2015

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CE DECLARATION OF CONFORMITY

17th Edition of 30/08/2018 -Version of 09/07/2020

According to Appendix II of the Directive 93/42/CEE Regarding Medical Devices (D.Lgs February 24 1997, n. 46) and successive amendments and integrations

The undersigned **permedica spa,** with legal offices in Via Como, 38 - 23807 Merate (LC) Italy and operative units in Via Como, 38 and 39 – 23807 Merate (LC), manufacturer of medical devices called:

ORTHOPAEDIC DEVICES AND RELATIVE ACCESSORIES: FEMORAL STEMS

(whose codes and trade names are specified in the appendix)

declares, under its own responsibility, that:

1. the devices in question meet all the applicable dispositions of Directive 93/42/EEC and successive amendments and integrations on Medical Devices, and in particular the essential requirements of Appendix I;
2. the devices in question meet the requisites of the attached standards;
3. the devices in question are to be considered as belonging to **Class IIb** in compliance with the Rule n. 8 of Appendix IX of Directive 93/42/EEC and successive amendments and integrations on Medical Devices or to **Class III** in compliance with Directive 2005/50/CE relative to the reclassification of hip, knee and shoulder joint prostheses, which modifies classification criteria of Appendix IX of Directive 93/42/EEC (in the appendix the product class is specified);
4. the devices in question are commercialised in **STERILE** packs;
5. undertakes to maintain the technical product dossier, as well as the design, production and control registrations (batch records) for a period of at least fifteen years from the last date of manufacture of the last product batch, and to make the same available to the Notified Body and Competent National Authority;
6. the devices in question are manufactured and placed on the market according to the product technical dossier located within the company quality management system in compliance with standards UNI CEI EN ISO 13485: 2016 (Certificate n. **375DM06** released by Certification Body ITALCERT, viale Sarca, 336 – 20126 Milan – Italy).
7. has instituted and maintains a suitable procedure to guarantee after-sales surveillance required by Directive 93/42/EEC and successive amendments and integrations in accordance with European guide MEDDEV 2.12-1.

Notified Body: **ITALCERT** (code 0426) Viale Sarca, 336 - 20126 MILANO -Italy
Certificate n.: **071-02-03-DM**
Date of first release: 2007-07-02 Expiration date: 2022-07-01.

This Declaration of Conformity has a validity of 15 years.

Merate, 09/07/2020 Marco Perego (General Manager): _____

Appendices:

- Product codes list (total pages n. 2)
- Standards references list (total pages n. 2)

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Attached to the CE DECLARATION OF CONFORMITY Femoral Stems - Hip System
Date: 09/07/2020

Code	Description	Class
11901	EXACTA HaX-Pore Femoral Stem – size 1	III
11902	EXACTA HaX-Pore Femoral Stem - size 2	III
11903	EXACTA HaX-Pore Femoral Stem - size 3	III
11904	EXACTA HaX-Pore Femoral Stem - size 4	III
11905	EXACTA HaX-Pore Femoral Stem - size 5	III
11906	EXACTA HaX-Pore Femoral Stem - size 6	III
11907	EXACTA HaX-Pore Femoral Stem - size 7	III
11908	EXACTA HaX-Pore Femoral Stem - size 8	III
11929	*EXACTA HaX-Pore Femoral Stem - size 9 (on request)*	III
11930	*EXACTA HaX-Pore Femoral Stem - size 10 (on request)*	III
11931	*EXACTA HaX-Pore Femoral Stem - size 11 (on request)*	III
11932	*EXACTA HaX-Pore Femoral Stem - size 12 (on request)*	III
11911	EXACTA LATERAL HaX-Pore Femoral Stem - size 1	III
11912	EXACTA LATERAL HaX-Pore Femoral Stem - size 2	III
11913	EXACTA LATERAL HaX-Pore Femoral Stem - size 3	III
11914	EXACTA LATERAL HaX-Pore Femoral Stem - size 4	III
11915	EXACTA LATERAL HaX-Pore Femoral Stem - size 5	III
11916	EXACTA LATERAL HaX-Pore Femoral Stem - size 6	III
11917	EXACTA LATERAL HaX-Pore Femoral Stem - size 7	III
11918	EXACTA LATERAL HaX-Pore Femoral Stem - size 8	III
11937	*EXACTA LATERAL HaX-Pore Femoral Stem - size 9 (on request)*	III
11938	*EXACTA LATERAL HaX-Pore Femoral Stem - size 10 (on request)*	III
11939	*EXACTA LATERAL HaX-Pore Femoral Stem - size 11 (on request)*	III
11940	*EXACTA LATERAL HaX-Pore Femoral Stem - size 12 (on request)*	III
11701	EXACTA PLUS Femoral Stem - size 1	III
11702	EXACTA PLUS Femoral Stem - size 2	III
11703	EXACTA PLUS Femoral Stem - size 3	III
11704	EXACTA PLUS Femoral Stem - size 4	III
11705	EXACTA PLUS Femoral Stem - size 5	III
11706	EXACTA PLUS Femoral Stem - size 6	III
11707	EXACTA PLUS Femoral Stem - size 7	III
11708	EXACTA PLUS Femoral Stem - size 8	III
11729	EXACTA PLUS Femoral Stem - size 9 (on request)	III
11730	EXACTA PLUS Femoral Stem - size 10 (on request)	III
11731	EXACTA PLUS Femoral Stem - size 11 (on request)	III
11732	EXACTA PLUS Femoral Stem - size 12 (on request)	III
11711	EXACTA PLUS LATERAL Femoral Stem - size 1	III

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11712	EXACTA PLUS LATERAL Femoral Stem - size 2	III
11713	EXACTA PLUS LATERAL Femoral Stem - size 3	III
11714	EXACTA PLUS LATERAL Femoral Stem - size 4	III
11715	EXACTA PLUS LATERAL Femoral Stem - size 5	III
11716	EXACTA PLUS LATERAL Femoral Stem - size 6	III
11717	EXACTA PLUS LATERAL Femoral Stem - size 7	III
11718	EXACTA PLUS LATERAL Femoral Stem - size 8	III
11739	EXACTA PLUS LATERAL Femoral Stem - size 9 (on request)	III
11740	EXACTA PLUS LATERAL Femoral Stem - size 10 (on request)	III
11741	EXACTA PLUS LATERAL Femoral Stem - size 11 (on request)	III
11742	EXACTA PLUS LATERAL Femoral Stem - size 12 (on request)	III
88000	UNIVERSAL CEMENT RESTRICTOR	IIb

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Allegato della Dichiarazione di Conformità:
Attached to Declaration of Conformity:
Protesi Articolari e Relativi Accessori - Protesi d'Anca: Steli femorali
Joint Prostheses and Related Accessories – Hip Prostheses: Femoral stems

Elenco norme di riferimento / Standard List Preparató il 28/02/2020 – Emesso il 09/07/2020 Prepared on 28/02/2020 – Released on 09/07/2020		
Doc. n°	***Title***	***Ed. / Date***
UNI CEI EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	Mar. 2016
UNI EN ISO 14630	Non-active surgical implants — General requirements	Gen. 2013
UNI EN ISO 21534	Non-active surgical implants – Joint replacement implants- Particular requirements	Mag. 2009
UNI EN ISO 21535	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants	Mar. 2017
ISO 7206/1	Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions	01/04/08
ISO 7206/4	Implants for surgery. Partial and total hip joint prostheses Part 4: Determination of endurance properties of stemmed femoral components	15/06/10
ISO 7206/6	Implants for surgery. Partial and total hip joint prostheses. Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components	15/11/13
UNI CEI EN ISO 14971	Medical devices – Application of risk management to medical devices	Ott. 2012
ISO 5832/1	Implants for surgery Metallic materials Part 1: Wrought stainless steel	15/07/16
ISO 5832/2	Implants for surgery. Metallic materials. Part 2: Unalloyed titanium	15/07/99
ISO 5832/3	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6 – aluminium 4 – vanadium alloy	15/10/16
ISO 5832/9	Implants for surgery. Metallic materials. Part 9: Wrought high nitrogen stainless steel	15/06/07
ISO 5832/11	Implants for surgery. Metallic materials. Part 11: Wrought titanium 6 –aluminum 7- niobium alloy	15/09/14
ISO 5832/12	Implants for surgery. Metallic materials. Part 12: Wrought cobalt-cromium-molybdenum alloy	01/05/07

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ISO 5834/1	Implants for surgery. Ultra high molecular weight polyethylene Part 1: powder form	Feb. 2019
ISO 5834/2	Implants for surgery. Ultra high molecular weight polyethylene Part 2: Moulded form	Feb. 2019
ISO 13779/2	Implants for surgery. Hydroxyapatite. Coatings of hydroxyapatite	01/10/2008

UNI EN ISO 10993-1 (previous EN 30993-1: 1994)	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Apr. 2010

UNI CEI EN ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Mar. 2017
UNI CEI EN 1041	Information supplied by the manufacturer of medical devices	Dec. 2013

UNI EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Nov. 2017

UNI EN ISO 14644-1	Cleanrooms and associated controlled environments Part 1: Classification or air cleanliness by particle concentration	Feb. 2016
UNI EN ISO 14644-2	Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness concentration	Feb. 2016

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UNI EN ISO 11137-2	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose	Nov. 2015

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DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

Doc. n°: DOCAS-002/A Edizione 17.01

Doc. N°: DOCAS-002/A Edition 17.01

Dispositivi/*Devices*

PROTESI ARTICOLARI E RELATIVI ACCESSORI:
PROTESI D'ANCA – STRUMENTARIO CHIRURGICO MOTORIZZABILE E COMPONENTI DI PROVA PER COMPONENTI ACETABOLARI

(i cui codici e nomi commerciali sono specificati nell'allegato A)

JOINT PROSTHESIS AND RELATED ACCESSORIES:
HIP PROSTHESIS – SURGICAL INSTRUMENTS CONNECTABLE TO AN ACTIVE DEVICE AND TRIAL COMPONENTS FOR ACETABULAR COMPONENTS

(codes and commercial name are listed in the attachment A)

Destinazione d'uso/*Intended use*

Strumenti chirurgici da utilizzarsi per l'impianto di sistemi di protesi di anca.

Surgical instruments intended to be used for the implantation of hip joint systems.

Regola di Classificazione/*Classification Rule*

I dispositivi di cui all'oggetto appartengono alla **Classe IIa** in accordo alla Regola 6 dei Criteri di Classificazione dell'Allegato IX della Direttiva 93/42/CEE e successive integrazioni ed emendamenti ed in accordo a quanto riportato nel paragrafo 8.31 "Trial hip prosthesis heads or stems" del "Manual on borderline and classification in the community regulatory framework for medical devices".

*The devices in question are classified as **Class IIa** according to Rule 6 of classification criteria reported in Annex IX of Council Directive 93/42/EEC and subsequent integrations and amendments and according to paragraph 8.31 "Trial hip prosthesis heads or stems" of "Manual on borderline and classification in the community regulatory framework for medical devices".*

Dichiarazione/*Declaration*

Ai sensi dell'allegato II, escluso punto 4, della direttiva 93/42/CEE sui Dispositivi Medici (D.Lgs 24 febbraio 1997, n° 46) e successive integrazioni ed emendamenti, la scrivente **Permedica S.p.A,** con sede legale in via Como, 38 - 23807 Merate (LC) Italia e unità operative in via Como, 38 e 39 -23807 Merate (LC) Italia, Fabbricante dei dispositivi medici oggetto della presente dichiarazione di conformità, dichiara, sotto la propria responsabilità, che:

*According to Council Directive 93/42/EEC (legislation n°46 dated February 24 1997) concerning Medical Devices, Annex II - point 4 excluded, and subsequent integrations and amendments, **Permedica S.p.A.**, having its registered offices in via Como, 38 – 23807 Merate (LC) Italy and production plants in via Como, 38 and 39 – 23807 Merate (LC) Italy, Manufacturer of the medical devices object of the present declaration, declares under its own responsibility that:*

1. i dispositivi di cui all'oggetto soddisfano le disposizioni applicabili della Direttiva 93/42/CEE e successive integrazioni ed emendamenti e, in particolare, i pertinenti requisiti essenziali dell'Allegato I;
   the devices in question meet the applicable provisions of Council Directive 93/42/EEC and subsequent integrations and amendments and, in particular, meet the essential requirements listed in Annex I;
2. i dispositivi di cui all'oggetto sono fabbricati e posti in commercio secondo quanto indicato nel fascicolo tecnico di prodotto FTA-002 nell'ambito dell'applicazione di un Sistema di Gestione per la Qualità aziendale conforme alla norma UNI CEI EN ISO 13485:2016 (Certificato n. **375DM06** rilasciato dall'Ente Notificato ITALCERT viale Sarca, 336 – 20126 Milano – Italia).
   *the devices in question are manufactured and marketed according to information reported in the product technical file FTA-002 within the scope of a Quality Management System compliant to UNI CEI EN ISO 13485:2016 requirements (Certificate n. **375DM06** released by the Notified Body ITALCERT viale Sarca, 336 – 20126 Milan – Italy).*
3. i dispositivi di cui all'oggetto vengono forniti allo stato **NON STERILE.**
   *the devices in question are supplied in the **NON-STERILE** condition.*

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DICHIARAZIONE DI CONFORMITÀ CE

EC DECLARATION OF CONFORMITY

Doc. n°: DOCAS-002/A Edizione 17.01

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Allegati/*Attachments*:

- Allegato A - Elenco codici prodotto (totale pagine 1).
  Attachment A - List of product codes (total n° of pages 1).

Certificati/*Certificates*

Questa dichiarazione è supportata dai Certificati emessi dall'Ente Notificato:

This declaration is supported by the Certificates issued by the Notified Body:

ITALCERT n° identificazione/*identification n°*: 0426

Viale Sarca, 336 – 20126 MILANO

Italia/*Italy*

Certificato CE n°/*EC Certificate n°*: **071-02-04-DM**	Data di 1° rilascio/*1st issue date*: 2007-07-02 Data di scadenza/*expiry date*: 2022-07-01

La presente dichiarazione di conformità è conservata per 10 anni dall'immissione sul mercato dell'ultimo dispositivo

The present declaration of conformity is kept available for 10 years after the last device has been placed on the market.

Data preparazione/*Preparation date*: 20/11/2020	Approvata da/*Approved by* Marco Perego (Amministratore Unico/*Sole Administrator*):
Data validità/*Effective date*: 09/12/2020	Merate, 09/12/2020

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Attachment A to DoC n° DOCAS-002/A Edition 17.01

List of product codes

This document is a true extraction from the list of product codes attached to the original copy of the DoC.

Ref.	Description	Class
S35200	JUMP System /PEG INSTRUMENTS SET	IIa
S26900	Modular BI-ARTICULAR CUP INSTRUMENTS SET	IIa
S32700	JUMP SYSTEM Cemented Instruments Set	IIa
S38500	ACORN Cup INSTRUMENT SET	IIa

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ITALCERT

CERTIFICATO N° 375DM06

CERTIFICATE N° 375DM06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

PERMEDICA S.p.a.

Via Como, 38 – IT 23807 MERATE (LC)

nella Sede Operativa di
Operative Unit

Via Como, 38 – IT 23807 MERATE (LC)
Via Como, 39 – IT 23807 MERATE (LC)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Progettazione, produzione, immissione in commercio a proprio nome e assistenza post vendita di dispositivi medici impiantabili, accessori e strumenti per implantologia ossea. Produzione di dispositivi medici impiantabili, accessori e strumenti per implantologia ossea conto terzi. Commercializzazione e assistenza post-vendita di dispositivi medici impiantabili, accessori e strumenti per implantologia ossea.

Design, manufacture, placing on the market and post-marketing service of implantable medical devices, accessories and instruments for bone implantology. Manufacture of implantable medical devices, accessories and instruments for bone implantology on behalf of a third part. Marketing and post-marketing service of implantable medical devices, accessories and instruments for bone implantology.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiry Date*
2007-07-02	2019-07-02	2022-07-01

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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