CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23003	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2004-01-16	Valido da / *Valid from*	2019-01-12
Scadenza / *Valid until*	2024-01-15	Ultima modifica / *Last change date*	2020-11-21

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

PROJECT ENGINEERING S.r.l.

Sede Legale e Operativa / *Registered and Operational Headquarter:*
Via Colle Ramole, 9
50023 Impruneta, FI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Apparecchiature per il monitoraggio diretto della pressione del sangue / *Direct blood pressure monitoring equipments*
Apparecchiature per il monitoraggio diretto della pressione e saturazione del sangue / *Direct blood pressure and oxigen saturation monitoring equipments*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 23003	Revisione / *Revision*	10
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Apparecchiature per il monitoraggio diretto della pressione del sangue / *Direct blood pressure monitoring equipments*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
Bio-Si International

Modello / Model:
MostCare

Codici / Codes:
08MC01

Tipologia / *Medical Devices:*
Apparecchiature per il monitoraggio diretto della pressione e saturazione del sangue / *Direct blood pressure and oxigen saturation monitoring equipments*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
Bio-Si International

Modello / Model:
MostCareUp

Codici / Codes:
08MC02 Rel: XXY

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CERTIFICATE

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La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2021-02-01
N. Protocollo R 012

Spett.le / *Messrs.*

PROJECT ENGINEERING S.r.l.
Via Colle Ramole, 9
50023 Impruneta FI

OGGETTO: COMUNICAZIONE DI RIDUZIONE E MODIFICA DELLA CERTIFICAZIONE CE – PIANO DI CERTIFICAZIONE MED 23003
NOTICE OF REDUCTION AND MODIFICATION OF THE EC CERTIFICATION - CERTIFICATION PLAN MED 23003

Gentile Cliente,
Dear Customer,

Kiwa Cermet Italia, Organismo Notificato n. 0476, in accordo a quanto riportato nel rapporto di verifica del 02-03/11/2021 e da quanto da voi formalmente richiesto con lettera Rif: LE3143BSI.DOCX datata 22/10/2021, comunica di aver registrato per il certificato MED 23003 la riduzione della certificazione CE relativa al prodotto:

Kiwa Cermet Italia, Notified Body No. 0476, in accordance with the contents of the audit report dated 02-03/11/2021 and with what you formally requested by letter Ref: LE3143BSI.DOCX dated 22/10/2021, hereby informs you that have registered the reduction of the EC certificate MED 23003 relating to the following product:

MostCare - Codice 08MC01

e comunica inoltre, come indicato nel rapporto di verifica del 02-03/11/2021, l'aggiunta del codice MDS 7010 sul seguente prodotto:

and also notifies, as indicated in the audit report of 02-03/11/2021, the inclusion of MDS code 7010 on the following product:

MostCareUp - Codice 08MC02 Rel: XXY

A seguito di quanto sopra, Le comunichiamo che per il certificato:

As a result of the above reduction procedure, we inform you that for the CE Certificate:

Certificato CE MED 23003, Rev. 10, data di ultima modifica 21/11/2020
Certificate CE MED 23003, Rev. 10, last change date 21/11/2020

non sarà emessa nessuna ulteriore revisione a quanto attualmente in Sue mani, pertanto la presente dichiarazione dovrà essere sempre allegata al certificato in Suo possesso.

no further revision will be issued to what is currently in your possession, therefore this declaration must always be attached to the CE certificate in your possession.

Con l'augurio che la collaborazione con Kiwa Cermet Italia possa essere e mantenersi costruttiva anche in futuro, rimaniamo a disposizione per qualsiasi necessità.
Hoping the cooperation with Kiwa Cermet can always be positive and effective in the future, we remain at disposal for any other need.

Cordiali saluti,
Best regards,

Kiwa Cermet Italia
Medical Devices Division
Francesco Mina

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2023/09/20
CL1/V3

Esteemed

PROJECT ENGINEERING S.r.l
Via Colle Ramole, 9
50023 Impruneta FI

Notified Body Confirmation Letter Reference: CERBO0407121 Rev.3

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

PROJECT ENGINEERING S.r.l
Via Colle Ramole, 9
50023 Impruneta FI

SRN Number (if available): IT-MF-000009571

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.
Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or

exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MostCareUp e Opthaem 805750245MCUPES	Class IIb	MostCareUp	MED 23003 Revisione 10 Scadenza 15/01/2024

Confirmation Letter Revision History

Rev. *Rev.*	**Date** *Date*	**Action** *Azione*
0	2023/09/20	Initial issue

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111