CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31033	Revisione / *Revision*	3
Primo rilascio / *First issue date*	2011-09-16	Valido da / *Valid from*	2021-05-10
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-10

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:*

ETROPAL JSC

Sede Legale e Operativa / *Registered and Operational Headquarter:*
blvd. Rusky 191
02180 Etropole - Bulgaria

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:*

Kit sterili medicali / *Medical sterile kits*

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

Rif. rapporto di audit/ *Ref. audit report:* del/dtd 12-18-/1/2021, 1-2/2/2021

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 09:36:07

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31033	Revisione / *Revision*	3
Primo rilascio / *First issue date*	2011-09-16	Valido da / *Valid from*	2021-05-10
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-10

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Kit sterili medicali / *Medical sterile kits*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Biopsy kits

Codici / Codes:

CK-201; CK-202; CK-203

Modello / Model:

Custom made kits

Codici / Codes:

CK - 3XX; CK - 4XX; CK - 5XX; CK - 6XX

Modello / Model:

Dressing kits

Codici / Codes:

CK-101; CK-102; CK-103; CK-104; CK-105; CK-106; CK-107; CK-108; CK109; CK-110; CK-111; CK-112; CK-113; CK- 114; CK-115; CK-116; CK-117; CK-118; CK-119; CK-120; CK-121; CK-122; CK-123; CK-124; CK-125; CK-126; CK-127; CK-128; 129-CK; CK-210

Modello / Model:

Suture procedure kits

Codici / Codes:

CK-204; CK-205; CK-206; CK-207; CK-208; CK209

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

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 09:36:27

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31033	Revisione / *Revision*	3
Primo rilascio / *First issue date*	2011-09-16	Valido da / *Valid from*	2021-05-10
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-10

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.
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

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 09:36:49

Organismo Notificato n. 0476
Notified Body nr. 0476

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/06/03
CL1/V4a

Esteemed

NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France

Notified Body Confirmation Letter Reference: CERBO0330023 Rev.2 and CERBO0350624

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 S.p.a., 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:

NOVOMED GROUP
12-14 rue Sarah Bernhardt
92600 Asnières sur Seine
France
SRN Number: FR-MF-000022240

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 90/385/EEC (AIMDD) or 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/AIMDD 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

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 05/06/2024 08:23:01

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
/	/	/	/

Table 2: Devices covered by this letter and for which the NB is NOT 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Operating scissors 37001494KitCutSkin7N	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Kit For Suture Precisio 1' Kit For Suture "Precision" Micro Halsey Type Needle Holder Set de pose de suture Set de suture Needle holder 37001494KitSutureDeliv85	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Thin Dissecting forcep/ Adson micro forcep/ Micro Adson Dissecting Forcep without tooth/ Ultra thin Dissecting Adson Forcep with tooth/ Ultra thin Dissecting Adson Forcep without tooth 37001494KitTissueClampVA	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 GMED N° 0459
Kit for Hypodermic Implant Insertion / Kit for Hypodermic Implant Insertion – Pharmacy 37001494ImplantInserKitFDT	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate N°36982 rev 1. -Addendum n° 36981 rev. 2 Expiry date: 10/09/2023 -GMED N° 0459

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable sterile kits for removal of contraceptive implant/ Kit for hypodermic implant removal Extrimplant kit (for chemist)/ Kit for hypodermic implant removal Extrimplant kit 37001494ImplantRemovKitHT	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	- EC certificate N°36982 rev 1. - Addendum n° 36981 rev. 2 -Expiry date: 10/09/2023 -GMED N° 0459
Suture removal kits 37001494SuturRemSteKitXM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Dressing Kit 37001494WoundDressingB3	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Magill forceps - straight - 170mm Magill forceps - straight - 200mm Magill forceps - straight - 250mm Metallic staple removers 37001494WoundCareKitSte7P	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Metallic staple removers 37001494StapleRemoversA7	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282
Anatomical forcep Kocher forcep 37001494SwabsClampEV	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD17 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
GYN&CUBE pessary 37001494pessary82	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-EC certificate n° 36974 rev. 0 Addendum n° 36973 rev. 1 -Expiry date: 10/09/2023 -GMED N° 0459

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Kit for IUD Insertion 37001494InsertIUDKitSteFD	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Evolution double hysterometer 37001494SteKitHysteroMUL	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Cut clamp forceps 37001494ClampCutUmbDM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Long Scissors with Littauer Blades 37001494ScissorCutIUDXD	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
Metalic Cheron Forcep Cheron forcep Metallic Bengolea Forcep Evolution forceps 37001494SwabsForcepsPU	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 -Expiry date: 27/05/2024 - ECM N° 1282
DIU hook 37001494IUDRemovHookRM	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282
Pozzi Forcep pink Metallic Palmer Pozzi Forcep Metallic Pozzi Forcep 37001494PozziUterusU9	Class Is	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	-ECM20MDD16 rev.0 Expiry date: 27/05/2024 - ECM N° 1282

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Set de Chirurgie / Kit For Surgery 37001494KitForSurgeryAT	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	-EC certificate n° MED 31033: -Expiry date: 26/05/2024 -KIWA N° 0476
Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision" Set d'intervention "Haute Précision" / Kit For Procedure "High Precision" Set PREMIUM d'intervention "Haute Précision" / PREMIUM Kit for surgery kits "High Precision" 37001494SetinterventionPV	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	-EC certificate n° MED 31033: -Expiry date: 26/05/2024 -KIWA N° 0476
Set d'intervention Gold / Gold Surgery kit 37001494KitForSurgeryAT	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Set de détersion pour plaies chroniques/Cleaning kits for chronic wounds 37001494CleankitswoundW3		Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Pince Halstead courbe sans griffe / Curved Halstead Forcep without tooth Pince Halstead/Halstead forcep 37001494pincechirurgic4Z	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Ciseaux à Dissection Metzenbaum / Metzenbaum Dissection Scissors 37001494KitCutSkin7N	Class IIa	Identification of the corresponding device under MDD ☒ Same □ Substitute	- EC certificate n° 36980 rev. 1 - Addendum n° 36979 rev. 2 Expiry date: 10/09/2023 -GMED N° 0459 -EC certificate n° MED 31033 -Expiry date: 26/05/2024 -KIWA N° 0476

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Stylet gradué/Graduated stylus 37001494GraduatedstylusJR	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Set d'ablation de Suture Precisio 3' / Kit For Suture Removal Precisio 3' 37001494SuturRemSteKitXM	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476
Gyn & Push Pince à biopsie du col utérin / Gyn & Push Disposable cervix biopsy forceps 37001494PincebiopsieP9	Class IIa	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	EC certificate n° MED 31033: - Expiry date: 26/05/2024 -KIWA N° 0476

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
00	2024/06/03	Initial issue
01	2024/06/05	certificate information added

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