EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Click or tap here to enter text.

Registration No.: HD 2031101-1

Manufacturer: Chongqing Jinshan Science & Technology (Group) Co., Ltd
No.18, Nishang Road,
LiangLu Industrial City
Yubei District
401120 Chongqing
P.R. China

Products: Capsule Endoscopy Systems, PH Capsule Monitoring Systems, Controllable Stomach Capsule Systems, Impedance-pH Reflux Monitoring Systems, Disposable Impedance-pH catheters, Disposable pH catheters, Video Gastroscope Systems, Endoscopic Carbon Dioxide Regulation Units, Hysteroscopy Systems, Disposable Hysteroscopic Cannulas, Argon-enhanced electrosurgical system (Argon-enhanced electrosurgical system generator, Argon-enhanced open-surgery electrosurgical handpiece/electrode, Argon-enhanced endoscopic electrosurgical electrode), Endoscopic Irrigation Pump, Video Capsule endoscopy system capsule, Flexible Video Gastroscope, Endoscopic Insufflation Tubing Set

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 10917835-100

Effective date: 2021-05-10

Expiry date: 2024-05-26

Issue date: 2021-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Chongqing Jinshan Science & Technology (Group) Co., Ltd.
No.18, Nishang Road, LiangLu Industrial City, Yubei District,
401120 Chongqing,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 14, 2024

Notified Body Confirmation Letter
Reference. : JINSH_PLA_2024-04-12; order#10924333

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Chongqing Jinshan Science & Technology (Group) Co., Ltd.
No.18, Nishang Road, LiangLu Industrial City, Yubei District,
401120 Chongqing,
P.R. China
SRN Number (if available): CN-MF-000022776

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 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Samuel Qin

Certification body

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**
pH Capsule Monitoring Systems **Basic UDI-DI:** 69463328JSPH-3V5	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
pH capsule **Basic UDI-DI:** 69463328JSPC-1U8	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Controllable stomach capsule systems **Basic UDI-DI:** 69463328KKWSYB	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Impedance-pH Reflux Monitoring Systems **Basic UDI-DI:**	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197

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
69463328JSIpS27			
Disposable Impedance-pH catheter **Basic UDI-DI:** 69463328Ipcatheter3S	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Disposable pH catheter **Basic UDI-DI:** 69463328pcatheterG3	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Capsule Endoscopy Systems **Basic UDI-DI:** **69463328OES5N** **69463328TES6F** 69463328KKS5L	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Smart Capsule **Basic UDI-DI:** **69463328OEG4** **69463328TEGK** 69463328KKG4	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Controllable stomach capsule **Basic UDI-DI:** 69463328KKW5U	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Video Gastroscope System **Basic UDI-DI:** 69463328EGS4A	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Video Gastroscope **Basic UDI-DI:** 69463328EGFA	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Endoscopic CO2 Regulation Unit **Basic UDI-DI:** 69463328JSQBXQ	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197

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
Argon-enhanced electrosurgical system **Basic UDI-DI:** 69463328JSDDSVN	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2031101-1 NB# 0197
Argon-enhanced electrosurgical system generator **Basic UDI-DI:** 69463328JSDDWM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2031101-1 NB# 0197
Disposable Argon monopolar electrosurgical pencil **Basic UDI-DI:** 69463328JSDD-FBUY	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2031101-1 NB# 0197
Disposable Argon Probe **Basic UDI-DI:** 69463328JSDD-FGVA	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2031101-1 NB# 0197
Endoscopic Irrigation Pump **Basic UDI-DI:** 69463328JSFPXK	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197
Endoscopic Insufflation Tubing Set **Basic UDI-DI:** **69463328STHE** **69463328SPH6** **69463328WBGN** **69463328DTFZ** 69463328TTHH	Class IIa	N/A	Certificate # HD 2031101-1 NB# 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-14	JINSH_CL607_2024-05-14	Initial issue

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 041181 0034 Rev. 03

Manufacturer:

Biopsybell s.r.l.
Via A. Manuzio 24
41037 Mirandola (MO)
ITALY

Facility(ies):

Biopsybell s.r.l.
Via A. Manuzio 24, 41037 Mirandola (MO), ITALY

Product Category(ies):

Biopsy needles and sets, needles and sets for centring mammary lesions, needles and sets for infusions, biopsy systems, discectomy systems, vertebroplasty systems, kyphoplasty systems, systems for the pre-natal diagnosis and artificial insemination, heat and moisture exchangers (hmes) fou use in humidifying the gases during spontaneous breathing, introduction systems, systems for aspiration, processing and reinjection of autologous adipose tissue, systems for bone marrow explant

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: ITA1272058

Valid from: 2020-01-17
Valid until: 2024-05-26

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	G21 S.r.l
Manufacturer address and contact details	via S. Pertini, 8 41039 San Possidonio (MO) – ITALY phone: +39 0535 30312 e-mail: info@g-21.it
Single Registration Number (SRN) (if available)	IT-MF-000030085

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name	See attached schedule
Notified body number	See attached schedule
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed in the attached schedule
  - Directive Certificate(s) covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

    Choose applicable statements:

    ☐ Expired *before* 20 March 2023:

    ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

    ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

    ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

    Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

    ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

    ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

    ■ Expired/expires *after* 20 March 2023:

    Choose one applicable statement:

    ■ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

    ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

- ■ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

G21 S.r.l.

phone: +39 0535 30312

e-mail: info@g-21.it

Maurizio Foroni

The Legal Representative

DocuSigned by:
Maurizio Foroni
6933E7CD1832441...

San Possidonio, 16 May 2024

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: KeyFix Direct Access Needle Code: 900103	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: V-Access Code: VV 11 120 5	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: V-Access Code: VV 11 150 5	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: V-Access Code: VV 13 120 5	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: V-Access Code: VV 13 150 5	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: KeyFix Bone Cement Filler Cannula Code: 900097	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: KeyFix Bone Cement Filler Cannula Code: 900100	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: Winch Kyphoplasty Balloon Catheter 11G 15mm Code: 900027	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: Winch Kyphoplasty Balloon Catheter 11G 20mm Code: 900028	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: G1 20 Code: 800001	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G1 40 Code: 800002	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G3 20 Code: 800003	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G3 40 Code: 800004	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: G1A 20 Code: 800006	2221348CE01 2221348DE01	26/05/2024	DEKRA Certification B.V.; Notified Body n°: 0344	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G1A 40 Code: 800007	2221348CE01 2221348DE01	26/05/2024	DEKRA Certification B.V.; Notified Body n°: 0344	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G3A 20 Code: 800008	2221348CE01 2221348DE01	26/05/2024	DEKRA Certification B.V.; Notified Body n°: 0344	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: G3A 40 Code: 800009	2221348CE01 2221348DE01	26/05/2024	DEKRA Certification B.V.; Notified Body n°: 0344	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: V-FAST Code: 800036	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: V-STEADY Code: 800039	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA
Model: V-FAST DH Code: 800016	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	NA

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: KeyFix Bone Cement Filler Cannula for Screw Cementation Code: 900146	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: FLEX DRILL Code: 900212	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	Model: FLEX DRILL Code: 900187
Model: KeyFix Bone Drill Code: 900141	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: Biopsy Kit Code: VV 10 190 8	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: Biopsy Kit Code: VV 11 190 8	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: Biopsy Kit Code: VV 13 190 8	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: V-HP Gun Code: 900165	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: Disp. Mixing Bowl-O Code: 900050	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: PicoMix V Code: 900129	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: PicoMix Bowl Code: 900122	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: PicoMix Syringe 120g Code: 900123	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: PicoMix Syringe 180g Code: 900123-1	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: SpaceFlex Hip Code: 900005 10	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Hip Code: 900005 13	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: SpaceFlex Hip Code: 900005 15	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Shoulder Code: 900001 08 42 15	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Shoulder Code: 900001 10 42 15	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Shoulder Code: 900001 10 48 18	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Shoulder Code: 900001 12 42 15	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Shoulder Code: 900001 12 48 18	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb

G21 S.r.l.
via S. Pertini, 8
41039 San Possidonio (MO) – ITALY
www.g-21.it – info@g-21.it

phone +39 0535 30312
fax +39 0535 417332
VAT IT03208750368

R.E.A. MO 368109
Iscr.Reg.Imp. 03208750368
Cap. Stock € 113.145,00 i.v.

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Model: SpaceFlex Shoulder Code: 900001 14 48 18	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2027	Same model and code, but the device will be reclassified from class Is to class IIb
Model: SpaceFlex Knee Code: 900189 60	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: SpaceFlex Knee Code: 900189 70	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA
Model: SpaceFlex Knee Code: 900189 80	MED 28029_1	26/05/2024	Kiwa Cermet Italia S.p.A.; Notified Body n°: 0476	DEKRA Certification B.V.; Notified Body n°: 0344	31/12/2028	NA

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Biopsybell s.r.l.
Via A. Manuzio 24
41037 MIRANDOLA (MO)
ITALY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
041181	713257446	+39 3451127547 Federico.Pace@tuvsud.com		2024-02-06	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041181 0038 Rev. 00

Reference: 713257446

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: IT-MF-000011601

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 TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 041181 0038 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
6th February 2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Rachele Ruggeri
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Feb 6, 2024 09:16 GMT+1)

Michael Mauermeir
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Device 1 **Basic UDI-DI:** **8033860KYPFT05A1S3Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G2S 041181 0033 Rev. 02 NB #: 0123 - TÜV SÜD Product Service GmbH
Device 2 **Basic UDI-DI:** **8033860KYPFT05A9T**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G2 041181 0034 Rev. 03 NB #: 0123 - TÜV SÜD Product Service GmbH
Device 3 **Basic UDI-DI:** **8033860BIOEFT011SJ2**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G2S 041181 0033 Rev. 02 NB #: 0123 - TÜV SÜD Product Service GmbH
Device 4 **Basic UDI-DI:** **8033860BIOEFT01U5**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #: G2 041181 0034 Rev. 03 NB #: 0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 5 **Basic UDI-DI:** **8033860DISCFT01D77**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G2 041181 0034 Rev. 03 NB #: 0123 - TÜV SÜD Product Service GmbH

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Not Applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-02-06	713257446	Initial issue

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 28029_1	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2009-09-25	Valido da / *Valid from*	2019-09-24
Scadenza / *Valid until*	2024-05-25	Ultima modifica / *Last change date*	2019-09-24

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:*

G 21 S.r.l.

Sede Legale e Operativa / *Registered and operational headquarter:*
Via Sandro Pertini, 8
41039 San Possidonio, MO - 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:*

Ago accesso diretto per procedure di cifoplastica / *Direct Access needle for kyphoplasty procedures*
Ago per Vertebroplastica / *Needle for vertebroplasty*
Ago primo accesso per procedure di cifoplastica / *First Access needle for kyphoplasty procedures*
Cannula per l'iniezione di cemento osseo in procedure di cifoplastica / *Bone cement filler cannula for kyphoplasty procedures*
Catetere per cifoplastica / *Kyphoplasty Balloon Catheter*
Cemento Osseo Radiopaco / *Radiopaque bone cement*
Cemento Osseo Radiopaco per procedure di consolidamento vertebrale / *Radiopaque bone cement for Percutaneous Vertebral Augmentation (PVA) procedures*
Dispositivo per l'accesso percutaneo nel corpo vertebrale / *Device for the percutaneous access to the vertebral body*
Dispositivo per l'iniezione di cemento osseo in viti peduncolari / *Device for the injection of bone cement in pedicle screw*
Filo guida per procedure di cifoplastica / *Guide wire for kyphoplasty*
Filo guida per procedure di cifoplastica, punta trocar / *Guide wire for kyphoplasty, trocar tip*
Fresa ossea per l'ingresso nel corpo vertebrale / *Drill for the entrance in the vertebral body*
Kit di Cemento Osseo, miscelatore e siringhe / *Bone cement, mixer and syringes kit*
Kit per biopsia ossea / *Kit for Bone Biopsy*
Kit per procedure di vertebroplastica / *Kit for Vertebroplasty procedures*
Pistola per iniezione di cemento osseo ad alta pressione / *High pressure gun for bone cement injection*
Sistema aperto di miscelazione di cemento osseo / *Open mixing system for bone cement preparation*
Sistema chiuso di miscelazione ed iniezione di cemento osseo / *Closed bone cement mixing and delivery system*
Stampo monouso per spaziatore modulare / *Disposable custom modular spacer mold*

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/dated 25-27/06/2019

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 27/06/2019

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:35:42

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Ago accesso diretto per procedure di cifoplastica / *Direct Access needle for kyphoplasty procedures*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

KeyFix Direct Access Needle

Codici / Codes:

900103 / 900094

Tipologia / *Medical Devices:*
Ago per Vertebroplastica / *Needle for vertebroplasty*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

V-ACCESS

Codici / Codes:

VV xx yyy z
where xx= diametro / diameter, yyy= lunghezza / length, z= tipo di modello / model type

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:36:07

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Ago primo accesso per procedure di cifoplastica / *First Access needle for kyphoplasty procedures*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

KeyFix First Access Needle

Codici / Codes:

900139 / 900140

Tipologia / *Medical Devices:*
Cannula per l'iniezione di cemento osseo in procedure di cifoplastica / *Bone cement filler cannula for kyphoplasty procedures*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

KeyFix Bone Cement Filler Cannula

Codici / Codes:

900097 / 900100

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:36:35

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Catetere per cifoplastica / *Kyphoplasty Balloon Catheter*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Winch Kyphoplasty Balloon Catheter 11G 15mm / Winch Kyphoplasty Balloon Catheter 11G 20mm

Codici / Codes:

900027 / 900028

Tipologia / *Medical Devices:*
Cemento Osseo Radiopaco / *Radiopaque bone cement*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 0202, MDS 7006 Ethylene oxide gas sterilization (EOG), MDS 7006 Radiation, MDS 7006 Aseptic processing

Modello / Model:

G1 20 / G1 40 / G3 20 / G3 40 / G3 60

Codici / Codes:

800001 / 800002 / 800003 / 800004 / 800005

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:37:01

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Cemento Osseo Radiopaco per procedure di consolidamento vertebrale / *Radiopaque bone cement for Percutaneous Vertebral Augmentation (PVA) procedures*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 0202, MDS 7006 Ethylene oxide gas sterilization (EOG), MDS 7006 Radiation, MDS 7006 Aseptic processing

Modello / Model:

V-FIX / V-FAST/ V-STEADY / V-FIX DH / V-FAST DH

Codici / Codes:

800037 / 800036 / 800039 / 800017 / 800016

Tipologia / *Medical Devices:*
Dispositivo per l'accesso percutaneo nel corpo vertebrale / *Device for the percutaneous access to the vertebral body*

Classe di rischio / *Risk class:*
II a

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

Modello / Model:

KeyFix Working Cannula

Codici / Codes:

900117

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:37:26

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivo per l'iniezione di cemento osseo in viti peduncolari / *Device for the injection of bone cement in pedicle screw*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

KeyFix Bone Cement Filler Cannula for Screw Cementation

Codici / Codes:

900146

Tipologia / *Medical Devices:*
Filo guida per procedure di cifoplastica / *Guide wire for kyphoplasty*

Classe di rischio / *Risk class:*
II a

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

Modello / Model:

KeyFix Kirschner Wire

Codici / Codes:

900119

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:37:59

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Filo guida per procedure di cifoplastica, punta trocar / *Guide wire for kyphoplasty, trocar tip*

Classe di rischio / *Risk class:*
II a

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

Modello / Model:

KeyFix Kirschner Wire Diamond

Codici / Codes:

900121

Tipologia / *Medical Devices:*
Fresa ossea per l'ingresso nel corpo vertebrale / *Drill for the entrance in the vertebral body*

Classe di rischio / *Risk class:*
II a

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

Modello / Model:

KeyFix Bone Drill

Codici / Codes:

900141

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:38:39

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Kit di Cemento Osseo, miscelatore e siringhe / *Bone cement, mixer and syringes kit*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 0202, MDS 7006 Ethylene oxide gas sterilization (EOG), MDS 7006 Radiation, MDS 7006 Aseptic processing

Modello / Model:

V- Mix 01 / V-Mix 02 / V-Mix 03

Codici / Codes:

800045/ 800046/ 800047

Tipologia / *Medical Devices:*
Kit per biopsia ossea / *Kit for Bone Biopsy*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Biopsy Kit

Codici / Codes:

VV xx yyy 8

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:39:14

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Kit per procedure di vertebroplastica / *Kit for Vertebroplasty procedures*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Vertebroplasty Kit

Codici / Codes:

VK01 xx yyy z

Tipologia / *Medical Devices:*
Pistola per iniezione di cemento osseo ad alta pressione / *High pressure gun for bone cement injection*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

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

Modello / Model:

V-HP Gun

Codici / Codes:

900165

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:39:47

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Sistema aperto di miscelazione di cemento osseo / *Open mixing system for bone cement preparation*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

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

Modello / Model:

Disp Mixing Bowl-O /Disp Mixing Bowl-V

Codici / Codes:

900050 / 900051

Tipologia / *Medical Devices:*
Sistema chiuso di miscelazione ed iniezione di cemento osseo / *Closed bone cement mixing and delivery system*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

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

Modello / Model:

PicoMix V

Codici / Codes:

900129

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

PicoMix Bowl

Codici / Codes:

900122

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:40:28

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

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / *Reg. Number*	MED 28029_1	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2009-09-25	Valido da / *Valid from*	2019-09-24
Scadenza / *Valid until*	2024-05-25	Ultima modifica / *Last change date*	2019-09-24

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Sistema chiuso di miscelazione ed iniezione di cemento osseo / *Closed bone cement mixing and delivery system*

Modello / Model:

PicoMix Syringe 120g / PicoMix Syringe 180g

Codici / Codes:

900123 / 900123-1

Tipologia / *Medical Devices:*
Stampo monouso per spaziatore modulare / *Disposable custom modular spacer mold*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

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

Modello / Model:

SpaceFlex Hip

Codici / Codes:

900005 10/ 900005 13/ 900005 15

Modello / Model:

SpaceFlex Knee

Codici / Codes:

900189 60 / 900189 70

Modello / Model:

SpaceFlex Shoulder

Codici / Codes:

900001 08 42 15 / 900001 10 42 15 / 900001 10 48 18 / 900001 12 42 15 / 900001 12 48 18 / 900001 14 48 18

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:41:12

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 28029_1	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2009-09-25	Valido da / *Valid from*	2019-09-24
Scadenza / *Valid until*	2024-05-25	Ultima modifica / *Last change date*	2019-09-24

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/09/2019 16:42:04

Organismo Notificato n. 0476
Notified Body nr. 0476