



Reg. Numero /
Reg. Number

MED 25033

Revisione /
Revision

9

Primo rilascio /
First issue date

2009-11-30

Valido da /
Valid from

2018-11-05

Scadenza /
Valid until

2023-12-15

Ultima modifica /
Last change date

2020-12-29

Pagina / Page 1 di / of 3

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:*

TEMA SINERGIE S.p.A.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via Malpighi 120
48018 Faenza, RA - 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:*

Infusore portatile di radiofarmaci / *Portable injector of radiopharmaceuticals*
Sistema trasportabile automatico di frazionamento / *Portable automatic dose drawing system*
Unità di frazionamento automatico delle dosi / *Automatic dose drawing station*

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 15/09/2020

Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 25033

Revisione /
Revision

9

Primo rilascio /
First issue date

2009-11-30

Valido da /
Valid from

2018-11-05

Scadenza /
Valid until

2023-12-15

Ultima modifica /
Last change date

2020-12-29

Pagina / Page 2 di / of 3

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Infusore portatile di radiofarmaci / Portable injector of radiopharmaceuticals

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101

Marca / Brandname:

TEMA SINERGIE

Modello / Model:

RAD-INJECT Y

Modello / Model:

RAD-INJECT B

Tipologia / Medical Devices:

Sistema trasportabile automatico di frazionamento / Portable automatic dose drawing system

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1101

Marca / Brandname:

TEMA SINERGIE

Modello / Model:

KARL100

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



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero /
Reg. Number

MED 25033

Revisione /
Revision

9

Primo rilascio /
First issue date

2009-11-30

Valido da /
Valid from

2018-11-05

Scadenza /
Valid until

2023-12-15

Ultima modifica /
Last change date

2020-12-29

Pagina / Page 3 di / of 3

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Unità di frazionamento automatico delle dosi / Automatic dose drawing station

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1101

Marca / Brandname:

TEMA SINERGIE

Modello / Model:

μDDS-A

Modello / Model:

μDDS-A ADD-SHIELD

Modello / Model:

μDDS-A STAND ALONE

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



Organismo Notificato n. 0476
Notified Body nr. 0476



Esteemed

TEMA SINERGIE S.p.A.
Via Malpighi, 120 - Faenza (RA) 48018 – Italia

Notified Body Confirmation Letter Reference: CERBO0551321 rev.1

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:

TEMA SINERGIE S.p.A.
Via Malpighi, 120 - Faenza (RA) 48018 – Italia
SRN Number (if available): not available yet

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

Alessia Frabetti

Firmato digitalmente
da: ALESSIA
FRABETTI
Data: 25/09/2023
08:51:08



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
RAD-INJECT γ 8056351100000RADINH4	Class IIb non- implantable	N/A	Certificate MED 25033 rev.9 expiry date 15/12/2023 CE 0476
RAD-INJECT β 8056351100000RADINH4	Class IIb non- implantable	N/A	Certificate MED 25033 rev.9 expiry date 15/12/2023 CE 0476

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	MDD 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

Rev. Rev.	Date Date	Action Azione
00	22/09/2023	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

