CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31144	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2013-07-29	Valido da / *Valid from*	2018-07-10
Scadenza / *Valid until*	2023-07-28	Ultima modifica / *Last change date*	2018-07-10

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:*

ADIRAMEF S.r.l.

Sede Operativa / *Operational Headquarter:*
Strada Consortile, S.n.c.
81032 Carinaro, CE - Italia

Sede Legale / *Registered Headquarter*
Via Ben Hur, 72
80126 Napoli, NA - 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:*

Autoclavi di sterilizzazione a vapore / *Steam sterilizers*
Frigoemoteca / *Blood bank refrigerators*
Sistemi di distribuzione gas medicali e vuoto / *Medical gas/vacuum pipeline systems*
Sistemi di evacuazione gas medicali anestetici / *Anesthetic gas evacuation pipeline*

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:* 15/06/2018 - 04-05/07/2018

Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31144	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2013-07-29	Valido da / *Valid from*	2018-07-10
Scadenza / *Valid until*	2023-07-28	Ultima modifica / *Last change date*	2018-07-10

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Autoclavi di sterilizzazione a vapore / *Steam sterilizers*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1107

Marca / *Brandname:*
Adiramef

Modello / Model:

Adirsat

Codici / Codes:

AD290550E; AD445DZZα; ADdddzzzα; ADyyyXZZα; ADYYXXZZZα; ADYYYXXZZZα; ADYYYXXXZZZα

Legenda / *Key:*

x = altezza camera/ *chamber height*

y = larghezza camera/ *chamber width*

z= profondità camera/ *chamber depth*

d=diametro camera/chamber diameter

α = E (generatore interno/*internal generator*) - V (vapore esterno/*external steam*)

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Chief Operating Officer
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Organismo Notificato n. 0476
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CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31144	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2013-07-29	Valido da / *Valid from*	2018-07-10
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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:*
Frigoemoteca / *Blood bank refrigerators*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1101

Marca / *Brandname:*
Adiramef

Modello / Model:

Adirfree

Codici / Codes:

XXXX Y PZ W Legenda/Key: X= capacità netta in litri/ net capacity in liters Y= numero di porte / number of doors Z = C (porta cieca / blind door) , V (porta vetro / glass door) W = H (alta temperatura / high temperature), L (bassa temperatura / low temperature)

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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di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2022/10/10
Codice: CERBO0243922

Spett.le

NOME AZIENDA e RAGIONE SOCIALE precedente: ADIRAMEF S.r.l.
NOME AZIENDA e RAGIONE SOCIALE attuale: ADIRAMEF S.p.A.
PIVA: 07777350633
Strada Consortile s.n.c.
81032, Carinaro (CE)

Oggetto: Nulla Osta per "cambio Ragione sociale" relativo al Piano di Certificazione MED 31144 in conformità ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni

Gentile Cliente,

In accordo all'Art 120, comma 3, del MDR e alla linea guida -MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD si ritiene la seguente modifica non significativa. alla progettazione o alla destinazione d'uso del dispositivo.

Kiwa Cermet Italia, Organismo Notificato n. 0476, a seguito dell'esito positivo della attività di valutazione e di delibera di quanto in oggetto, con piacere comunica che la Sua Azienda ha ricevuto il

Nulla Osta

Alla modifica relativa al cambio di Ragione sociale e all'immissione in commercio dei relativi dispositivi medici a far data dalla presente comunicazione.

A seguito di quanto sopra e in virtù dell'Art. 120, comma 1, del MDR, non sarà emessa nessuna ulteriore revisione del certificato CE attualmente in Suo possesso, che rimane valido e registrato come:

Certificato CE MED 31144, rev. 7, data di ultima modifica 13/05/2020

La presente dichiarazione dovrà essere sempre allegata al certificato in Suo possesso.

Vi ricordiamo di farci pervenire su carta intestata, l'identificazione del primo lotto che sarà immesso in commercio a seguito della modifica di cui sopra.

Con l'augurio che la collaborazione con Kiwa Cermet Italia possa essere e mantenersi costruttiva anche in futuro, rimaniamo a disposizione per qualsiasi necessità e porgiamo

Cordiali saluti

Kiwa Cermet Italia
Medical Devices Division
Roberto Sanavio

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2023/07/07
CL1/V3

Esteemed

Adiramef S.p.a.
Via Ben Hur 72 – 80126 Napoli (NA)

Notified Body Confirmation Letter Reference: CERBO0232823 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:

Adiramef S.p.a.
Via Ben Hur 72
80126 Napoli (NA)
SRN Number: IT-MF-000021625

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
Frigoemoteca (805689321FRIGOEADIRAMEFMJ)	Class IIa	N/A	Certificate MED 31144 rev.7 , expiry date 31/12/2028 ; NB 0476
Impianto di distribuzione gas medicali (805689321IDGMEDADIRAMEFZ9)	Class IIb	N/A	Certificate MED 31144 rev.7 , expiry date 31/12/2028 ; NB 0476
Impianto di distribuzione vuoto (805689321IDVUOTADIRAMEFF4)	Class IIb	N/A	Certificate MED 31144 rev.7 , expiry date 31/12/2028 ; NB 0476
Impianto di evacuzione gas anestetici (805689321IEGANEADIRAMEFXS)	Class IIa	N/A	Certificate MED 31144 rev.7 , expiry date 31/12/2028 ; NB 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	2023/07/07	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

Contatti:
Tel.: +39 081 195 37 701
Fax: +39 081 891 45 24
Numero Verde: 800 078 563
Web: www.adiramef.it
E-mail: info@adiramefspa.com

Sede Legale: Via Ben Hur, 72 - 80126 Napoli (NA)
Amministrazione, Laboratori, Stabilimento di Produzione:
Strada Consortile, s.n.c. - 81032 Carinaro (CE) – P.I. 07777350633

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- 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	ADIRAMEF SPA
Manufacturer address and contact details	Via Ben Hur 72 80126 Napoli (NA), TEL. 08119537701 E-MAIL info@adiramefspa.com
Single Registration Number (SRN) (if available)	IT-MF-000021625
Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	
Notified body name (if applicable)	KIWA CERMET ITALIA SPA □ See attached schedule
Notified body number (if applicable)	NB 0476 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	MED 31144 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Adiramef S.p.A.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- 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,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were 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.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Adiramef S.p.A.

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☐ 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.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

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 substitutes 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.

☒ 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.

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- **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:

Adiramef s.p.a.

Napoli, 09/05/2024

Sole Director (legal rappresentative) Concetta Scodellaro

Contact Details (at least email)

info@adiramefspa.com

Ing. Diego Giansanti , tel. +39 3485861808, e-mail diego.giansanti@adiramefspa.com

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Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
FRIGOEMOTECA	**MED 31144**	**28/07/2023**	**NB 0476**	**NB 0476**	**31/12/2028**	
IMPIANTO DI DISTRIBUZIONE GAS MEDICALI	**MED 31144**	**28/07/2023**	**NB 0476**	**NB 0476**	**31/12/2028**	
IMPIANTO DI DISTRIBUZIONE VUOTO	**MED 31144**	**28/07/2023**	**NB 0476**	**NB 0476**	**31/12/2028**	
IMPIANTO DI EVACUAZIONE GAS ANESTETICI	**MED 31144**	**28/07/2023**	**NB 0476**	**NB 0476**	**31/12/2028**	
AUTOCLAVE DI STERILIZZAZIONE A VAPORE SATURO	**MED 31144**	**28/07/2023**	**NB 0476**	**NB 0476**	**26/05/2024**	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)