CERTIFICATO CE
EC CERTIFICATE

n. **ECM19MDD002 rev.2**

Data di prima emissione * *Date of first issue*	*13/11/2017*
Data di emissione *Date of issue*	*18/02/2019*
Data di ultimo rinnovo *Date of last renewal*	*10/12/2019*
Data di revisione *Date of revision*	*24/05/2021*
Data di scadenza *Expiry date*	*27/05/2024*

CERTIFICATO CE
EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente
Applicant

Ragione Sociale *Company Name*	C.B.M. s.r.l. a socio unico
Sede Legale *Legal address*	Via Castello 10, 26038 Torre de' Picenardi Cremona (CR)
Località *Place*	Italia *Italy*
Sito produttivo *Place of production*	Idem *same as above*
Dispositivo Medico *Medical device*	*Piccoli sterilizzatori a vapore e a secco* *Small Steam Sterilizers and Dry Sterilizers*
Identificato come *Identified as*	Vedi allegato al presente certificato *See the annex of this certificate*

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità in accordo all'allegato II (escluso punto 4) della direttiva 93/42/CEE) e ha rilevato che ne soddisfa i requisiti.
Si fa riferimento al rapporto di audit di emissione del presente certificato del 04/10/2019; rif. piano di certificazione: CBM-18.07

ECM, Notified Body n° 1282 has verified the Quality System in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements.
Reference to the audit report related to issue of the present certificate dated 4th/10/2019; ref. certification plan: CBM-18.07

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

*certificato rilasciato per la prima volta da altro Organismo di Certificazione
certificate issued for the first time by another Certification Body

Ente Certificazione Macchine srl
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CERTIFICATO CE
EC CERTIFICATE

n. **ECM19MDD002 rev.2**

Data di prima emissione * *Date of first issue*	*13/11/2017*
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Allegato al Certificato CE
Annex to EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Descrizione ***Description***	**Classe di rischio** ***Risk class***	**Codice NBOG** ***NBOG code***	**Modello** ***Model***	**Taglie** ***Sizes***
Steam Sterilizers Fractionated Vacuum	IIb	MD1107 + MDS7010	SST1700B SST1700B+P SST1700B/W SST1700B/W+P SST2200B SST2200B+P SST2200B/W SST2200B/W+P SST2200BHD	/
Dry sterilizers	IIb	MD1107 + MDS7010	Panacea: 2429, 2430, 2431, 2429/A, 2430/A, 2431/A, 2432, 2433; Ministeril: 427; Microsteril: 436, 437, 438, 439	/

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

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MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/04/12
CL1/V4a

Esteemed

C.B.M. S.r.l. a socio unico
Via Castello, 10 - 26038 Torre dé Picenardi (CR) Italia

Notified Body Confirmation Letter Reference: CERBO0272723 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 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:

C.B.M. S.r.l. a socio unico
Via Castello, 10 - 26038 Torre dé Picenardi (CR) Italia

SRN Number (if available): IT-MF-000021066

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: 22/09/2024 18:11:13

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
Piccolo sterilizzatore a vapore con vuoto frazionato (805728901STEAM-STERIL—PS)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate ECM19MDD002 rev.2; NB#1282
Sterilizzatore a secco a controllo elettronico (805728901DRY-STERILIZ—WW)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate ECM19MDD002 rev.2; NB#1282

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/12	Rev.0	Initial issue
2024/09/20	Rev.1	Update of Table 1 and Table 2, following the signature of appropriate surveillances' offer

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