



Reg. Number	1248 - M	Valid from	2024-07-10
First issue date	2013-01-29	Last change date	2024-07-10
Valid until	2027-10-01		

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Quality Management System Certificate **UNI CEI EN ISO 13485:2021**

We certify that the Quality Management System of the Organization:

TEMA SINERGIE S.p.A.

is in compliance with the Standard UNI CEI EN ISO 13485:2021 for the following products/services:

Design, manufacturing, placing on the market and after-sales assistance of medical devices and systems for the containment, handling and monitoring of sterile radioactive substances. Marketing and after-sales assistance of medical devices for radiation therapy and nuclear medicine.

Medical Devices Division Manager

Alessia Frabetti

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 2 pages. The following technical datasheet provides details concerning the scope of certification.

TEMA SINERGIE S.p.A. Registered Headquarters

Via Malpighi 120 48018 Faenza (RA) Italia

Certified sites

Refer to the attached Technical Data Sheet for details of the locations

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
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CERMET



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Data sheet attached to the Certificate
UNI CEI EN ISO 13485:2021

TEMA SINERGIE S.p.A.
Certified sites:

Via Malpighi 120 48018 Faenza (RA) Italia

Medical Devices Division Manager
Alessia Frabetti

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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