



Reg. Number	18689 - M	Valid from	2024-05-02
First issue date	1997-09-23	Last change date	2024-05-02
Valid until	2027-06-01		

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

We certify that the Quality Management System of the Organization:

### **SIARE ENGINEERING INTERNATIONAL GROUP S.p.A.**

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

Design, production, placing on the market and post-market technical assistance of:

- Anaesthesia devices;
- Pulmonary ventilators for non-hospital use;
- Portable pulmonary ventilators;
- Adult and paediatric/neonatal pulmonary ventilators;
- Various instruments for anaesthesia and pulmonary ventilation support-hardware accessories.

Marketing of accessories for assistance and control of pulmonary ventilation and anesthesia.

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.

The date of issuance of this certificate is the date of first issue by another accredited body.

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

#### **SIARE ENGINEERING INTERNATIONAL GROUP S.p.A.**

##### **Registered Headquarters**

Via Giulio Pastore, 18 Località Crespellano 40053 Valsamoggia (BO) 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,  
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Data sheet attached to the Certificate  
**UNI CEI EN ISO 13485:2021**

**SIARE ENGINEERING INTERNATIONAL GROUP S.p.A.**  
**Certified sites:**

**Via Giulio Pastore, 18 Località Crespellano 40053 Valsamoggia (BO) Italia**

**Via Fini, 8/10 Località Crespellano 40053 Valsamoggia (BO) Italia**

Medical Devices Division Manager  
Alessia Frabetti

CERTIFICATE

**Kiwa Cermet Italia S.p.A.**  
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**CERMET**



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