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|------------------|------------|------------------|------------|
| Reg. Number      | 8315 - M   | Valid from       | 2025-03-05 |
| First issue date | 2010-03-10 | Last change date | 2025-03-05 |
| Valid until      | 2028-03-09 |                  |            |

## Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

### **SACACE BIOTECHNOLOGIES S.r.l.**

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

Development and production of diagnostic kits

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 1 pag.

#### **SACACE BIOTECHNOLOGIES S.r.l.** **Registered Headquarters**

Via Santisi SNC 82019 Sant'Agata De' Goti (BN) Italia

#### **Certified sites**

Via Scalabrini 44 22100 Como Italia

# CERTIFICATE

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

