



Reg. Number	9675 - M	Valid From	2018-09-14
First issue date	2012-10-03	Last change date	2018-09-14
Valid until	2021-10-02		

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

We certify that the Quality Management System of the Organization:

ENABLE INNOVATIONS S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and manufacturing of low volume aseptic filling sterile liquid medical devices (not injectable).
Manufacturing of low volume aseptic filling sterile liquid medical devices (not injectable) on customer's specifications

Chief Operating Officer
Giampiero Belcredi

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

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
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ENABLE INNOVATIONS S.r.l.

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Certified Sites

- Via Claudio Tolomeo 20/4 41012 Carpi (MO) Italia



SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C