



Reg. Number	10274 - M	Valid From	2018-11-29
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Valid until	2021-11-29		

Quality Management System Certificate
ISO 13485:2016

We certify that the Quality Management System of the Organization:

HYGIENE MEDICAL INDUSTRY CO. LTD

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

Production of disinfectants and cold sterilants for medical devices.
 Design and manufacture of disinfectants for use on surgical instruments, disinfectants for use on medical equipment and infant incubators, inventory, anaesthetic, heat sensitive equipment, rigid and flexible endoscopes, cleaning/disinfecting products for automatic washers-disinfectors of surgical instruments, anaesthetic equipment, rigid and flexible endoscopes, disinfectants for use on dental instruments/equipment, disinfectants for use on hospital linen in operation rooms.

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

This certificate is composed of 1 page

CERTIFICATE

Kiwa Cermet Italia S.p.A.
 Società con socio unico,
 soggetta all'attività di
 direzione e coordinamento di
 Kiwa Italia Holding Srl

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HYGIENE MEDICAL INDUSTRY CO. LTD

Registered Headquarters

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Certified Sites

- 81 A Nikola Gabrovski Str. 05000 Veliko Tarnovo Bulgaria



SGQ N° 007A
 SGA N° 010D
 PRO N° 0695
 PSM N° 004E
 PRS N° 059C