

 Fleg Number
 10274 - M
 Valid From
 2018-11-29

 First issue date
 2009-11-30
 Last change date
 2018-11-29

 Valid unita
 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

Helle

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 CELEN ISO 13485-2016 requirements. The date of issuance of this certificate is the date of first issue by enother accredited body. This certificate is composed of 1 page.

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

na Cadhano, 23 Iol:57 Granaroko del Europa

Tel +33.051.469.0.111 Fax +39.051.763.382 E-mail: info@ktivacermet.it ozway ktwa.it



HYGIENE MEDICAL INDUSTRY CO. LTD

Registered Headquarters - 81 A Nikola Gabrovski Str. 05000 Veliko Tarnovo Bulgaria Certified Sites 81 A Nikola Gabrovski Str. 05000 Veliko Tarnovo Bulgaria



SGQ N° 007A SGA N°-010D PRC N° 0695 PSM N° 0041