



Reg. Number	11459 - M	Valid From	2018-01-12
First issue date	2012-01-15	Last change date	2019-02-26
Valid until	2021-01-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

MACROMEDICS BV

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

Design, production and sale of medical devices for radiotherapy and radiodiagnostics

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.

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

Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it

MACROMEDICS BV

Registered Headquarters

- Kouwe Hoek 18, 2741 PX Waddinxveen Holland

Certified Sites

- Kouwe Hoek 18, 2741 PX Waddinxveen Holland



SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C