







Reg. Number M Valid from 2024-10-22

First issue date 2018-09-21 Last change date 2024-10-22

Valid until 2027-09-20

Previous expiration 2024-09-20 Page 1 of 2

Quality Management System Certificate

UNI CEI EN ISO 13485:2021

We certify that the Quality Management System of the Organization:

Granula Group

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

Production and R&D of: Color-, additive-, combi- masterbatches, dryblends and the corresponding services in the medical field

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.

Details of the processes/services carried out at the individual sites listed above are contained in the relevant certificates $n.\,17359$ AG-M and 17359 DE-M.

This certificate is composed of 2 pag. The following technical datasheet provides details concerning the scope of certification.

Granula Group

Registered Headquarters

Industrie Nord, 27 CH 5634 Merenschwand Switzerland

Certified sites

Refer to the attached Technical Data Sheet for details of the locations

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











17359 GROUP -

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Data sheet attached to the Certificate

UNI CEI EN ISO 13485:2021

Granula Group Certified sites:

Industrie Nord, 27 CH 5634 Merenschwand Switzerland

Production and R&D of: Color-, additive-, combi- masterbatches, dryblends and the corresponding services in the medical field

Fritz-Bolland-Str. 10, D-07407 Rudolstadt Germany

Production and R&D of: Color-, additive-, combi- masterbatches, dryblends and the corresponding services in the medical field

Fritz-Bolland-Str. 5, D-07407 Rudolstadt Germany

Warehouse

Medical Devices Division Manager Alessia Frabetti



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