

Certificate
19712 - M

kiwa

Valid from 2024-09-04 Last change date 2025-11-05
First issue date 2021-09-05 Valid until 2027-09-04

ISO 13485:2016

Quality Management System Certificate

We certify that the Quality Management System of the Organization:

Betatex S.p.A.

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

Design, manufacture and placement on the market of single-use medical devices, including operating theatre drapes, procedural sets and kits, related accessories, components and single-use surgical instruments, both sterile and non-sterile. Management of the production and placement on the market of aids for people with disabilities.

Kiwa Cermet Italia S.p.a.
Medical Devices
Director
Alessia Frabetti



The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
The date of issuance of this certificate is the date of first issue by another accredited body.
This certificate is composed of 2 pag. The following technical sheet provides details of the scope of certification.

Betatex S.p.A.

Registered Headquarters

Via Raffaello 2 06081 ASSISI (PG)

Certified sites

For details on the sites, please refer to the attached Technical Data Sheet

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Data sheet attached to the Certificate
ISO 13485:2016

Certified sites:

Viale Europa 06083 Bastia Umbra (PG)

Design, manufacture and placement on the market of single-use medical devices, including operating theatre drapes, procedural sets and kits, related accessories, components and single-use surgical instruments, both sterile and non-sterile. Management of the production and placement on the market of aids for people with disabilities.

Via dei Barrocciai, 2 06081 Santa Maria degli Angeli (PG)

Warehouse