



Reg. Number	19712 - M	Valid from	2024-09-04
First issue date	2021-09-05	Last change date	2024-09-04
Valid until	2027-09-04		

## Quality Management System Certificate **UNI CEI EN ISO 13485:2021**

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 marketing of single-use medical devices, operating theatre drapes, procedural sets and kits and related accessories, components and surgical instrumentation single-use, non-sterile and sterile.

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.

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 datasheet provides details concerning the scope of certification.

**Betatex S.p.A.**  
**Registered Headquarters**

Via Raffaello 2 06081 ASSISI (PG) Italia

**Certified sites**

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

CERTIFICATE



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Data sheet attached to the Certificate  
**UNI CEI EN ISO 13485:2021**

**Betatex S.p.A.**  
**Certified sites:**

**Viale Europa 06083 Bastia Umbra (PG) Italia**

Design, manufacture and marketing of single-use medical devices, operating theatre drapes, procedural sets and kits and related accessories, components and surgical instrumentation single-use, non-sterile and sterile.

**Località Venella snc 52044 Cortona (AR) Italia**

Design, manufacture and marketing of single-use medical devices, operating theatre drapes, procedural sets and kits and related accessories, components and surgical instrumentation single-use, non-sterile and sterile.

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

Warehouse

Medical Devices Division Manager  
Alessia Frabetti

CERTIFICATE

**Kiwa Cermet Italia S.p.A.**  
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soggetta all'attività di  
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www.kiwa.it

**CERMET**



MS N° 0007MS