

EC Certificate - Full Quality Assurance System No. 13 0040 QS/NB

The quality system of manufacturer

Green Implant MI Medical Technologie GmbH

Plauner Str. 163-165/13053 Berlin, Germany

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Endosseous Dental Implants and Accessories

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 23.07.2023 Valid until: 25.07.2026 First Issued: 22.01.2016

Revision: a

1023 Paul

Date: 23.07.2023 RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Annex to EC Certificate No. 13 0040 QS/NB

issued for manufacturer:

Green Implant MI Medical Technologie GmbH. Plauner Str. 163-165/13053 Berlin, Germany

Product(s):

Name: Dental Implants

Trade name(s): ---

Model(s): Classic Titanium Implant

Universal Titanium Implant Respect Titanium Implant Vector Titanium Implant Vector Plus Titanium Implant

Classic Plus Titanium

Angular Prefix for Plus Implant

Prefix for Plus Implant

Universal Plus Titanium Implant Prefix for Respect Plus Implant Respect Plus Titanium Implant Slim Prefix for Plus Implant Prestige Implant Kit Package Ideal Implant Kit Package Orthodontic Implant kit

Class:

GMDN: 42350, 55847, 55848, 55849

Date: 23.07.2023



Annex to EC Certificate No. 13 0040 QS/NB

issued for manufacturer:

Green Implant MI Medical Technologie GmbH. Plauner Str. 163-165/13053 Berlin, Germany

Name: Dental Abutments, Screws and

Superstructures

Trade name(s): ---

Model(s): Healing Screws

Straight Abutments

Straight Abutments with Shoulder

Angulated Abutments

Angulated Abutments with Shoulder

Plastic Abutments for Casting Straight Zirconium Abutments Angulated Zirconium Abutments Straight Abutments Prosthetic Set Angulated Abutments Prosthetic Set

Screw over Denture Abutments

Screw and Lock over Denture Abutments with Shoulder

Ball Abutments

Angular Adaptor System

Over Denture with Ball and Locator Abutments

Prosthetic Set

Abutments Locator

Abutments and Attachments Components

Screws

Class:

GMDN: 44879, 44880

Date: 23.07.2023





Annex to EC Certificate No. 13 0040 QS/NB

issued for manufacturer:

Green Implant MI Medical Technologie GmbH. Plauner Str. 163-165/13053 Berlin, Germany

Name: Drills and Accessories

Trade name(s): ---

Model(s): Surgical Drills

Surgical Drill Kit Package

Parallel/Depth Guide

Class:

GMDN: 32845, 45714, 41323, 32390, 16462, 31846

Name: Dental Bone Pins

Trade name(s): ---

Model(s): Surgical Support Screw

Titanium Bone Pins

Bone Grafting Kit

Class:

GMDN: 46536, 35868, 16101

Facility(ies):

Green Implant System Technologie Verwaltung GmbH. Plauner Str. 163-165/13053 Berlin, Germany

Date: 23.07.2023





Annex to EC Certificate No. 13 0040 QS/NB

issued for manufacturer:

Green Implant MI Medical Technologie GmbH. Plauner Str. 163-165/13053 Berlin, Germany

Certificate History:

Revision	Date	Reference Number	Action
	2016-01-22	803601812	Certification
a	2020-08-29	343603626	Change in manufacturer's name and address



Date: 23.07.2023