EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2158053-1

Manufacturer: **Guilin Woodpecker Medical Instrument Co., Ltd.**
Information Industrial Park,
Guilin National High-Tech Zone
Guilin
541004 Guangxi
P.R. China

EUDAMED Single Registration No.: CN-MF-000009139

Products: Products of class IIb:
Z110304 -DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY INSTRUMENTS
INSTRUMENTS FOR ENDORAL RADIOLOGY
- Dental X-Ray Generator

Products of class IIa:
Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS

Authorised representative(s): MedNet EC-REP C IIb GmbH
Borkstrasse 10·48163 Muenster·Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-07-31

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10920904-150

Effective date: 2023-07-31

Expiry date: 2028-07-30

Issue date: 2023-07-31

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.