EC Declaration of Conformity

For DENTIOIII, DENTIOIII-S

We herewith declare that the under-mentioned products are in conformity with the essential requirements and the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices, and is subject to the procedure set out in Annex II (excluding section 4) of MDD 93/42/EEC under the supervision of Notified Body Number 0197, TUV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg. All supporting documentation is retained under the premises of the manufacturer. The declaration of conformity is issued under sole responsibility of the manufacturer.

Product Name: **Dental X-ray System**

Model Name: **DENTIOIII, DENTIOIII-S**

Classification: **Class IIb (Directive 93/42/EEC as amended by 2007/47/EC)**

Conformity Assessment Route: **Annex II, Excluding Section 4, Directive 93/42/EEC as amended by 2007/47/EC**

Notified Body: **TÜV Rheinland TUV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg**

Standards applied: **IEC 60601-1:2005+A1:2012, IEC 60601-1-3:2008, IEC 60601-1-6:2010, IEC60601-2-63:2012, IEC60601-1-2:2014**

Manufacturers Registered Name: **HDX WILL Corp.**
#105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea

EC Representative: **KTR EUROPE GmbH**
Mergenthalerallee 77, 65760 Eschborn, Germany

Digitally signed by SACHDEV TATIANA
Date: 2022.06.25 09:38:00 EEST
Reason: MoldSign Signature
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CE 0197

Signature: HDX WILL JUNG, SANG JIN / CEO

Place/Date: Seoul, R.O.Korea, Dec. 13th, 2021

Sang-Jin Jung / CEO