



**ECOTRON Co., Ltd.**

4F & 5F, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-gu, Seoul 08511,  
Republic of Korea

## **EC Declaration of Conformity**

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the DoC.

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

**Model Name: DT-703, DT-703E**

**Product Serial Number:**

**Classification: Class IIb (Annex IX Rule 10, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)**

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

**Notified Body: TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße  
65 80339 Munich • Germany**

**Applied Standards: EN ISO 13485:2016, EN ISO 14971:2019, ISO 15223-1:2016,  
EN1041:2008, IEC60601-1:2005/AMD1:2012, EN60601-1-2:2015,  
IEC60601-1-3:2008/AMD1:2013, IEC60601-1-6:2010/AMD1:2013,  
IEC60601-2-65:2012/AMD1:2017, EN62304:2006/AC:2008,  
EN62366-1:2015, MEDDEV 2.7.1/Rev.4, MEDDEV 2.12.1/Rev.8,  
MEDDEV 2.12.2/Rev.2**

**EC Representative: OBELIS S.A Bd. General Wahis 53, 1030 Brussels, Belgium**

**EC Certificate: G1 092526 0008 Rev. 00**

**GMDN Code No.: 41256**

**CE 0123**

**Signature:**

**Date: SEP 22, 2021**

**Jun Yong Oh / President**