EU Declaration of Conformity

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

1) Manufacturer:

C&P Co., Ltd
1. #606 Centum Green Tower Bldg, 78 Centum jungang-ro, Haeundae-gu, Busan, South Korea 48059
2. SK Leader's View Bldg, 201 Eonju-ro, Gangnam-gu, Seoul, South Korea 06274
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2) European authorized representative:

CMC Medical Devices & Drugs S.L.
C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

3) Product Name:

Electronic Video Magnifier

4) Model Name:

i-1588, i-1788, ClearViewGO, Merlin mini,
ClearView GO(i-1588), ClearView GO(i-1788), Merlin mini(i-1588), Merlin mini(i-1788)

5) Basic UDI-DI:

8809833970007ED

6) Risk Class of the device:

Class I
In accordance with the rule 13 of Classification Rules set out in Annex VIII of Regulation (EU) 2017/745

7) Conformity Assessment Procedure:

Annex I, II, III and IV of Regulation (EU) 2017/745

8) Harmonised Standards:

Refer to Annex I

9) Additional information:

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:
C&P Co., Ltd.

CE

GS Lee, Director of C&P Co., Ltd

Busan, Republic of Korea; 2023-03-13.

Annex I

Standard	Reference of the standard
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 62304:2006	Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)