## G-CERTI Certificate

hereby certifies that

## **DURICO C&T INC.**

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

has been audited and certified as meeting the requirements & Scope of registration

ISO 13485:2016
Medical Devices - Quality Management Systems

Design, Development, Manufacture and Service of Special Paper (Thermal Paper, Ink-jet Paper, Photographic Paper, Mat Sheet)

Certificate No : GK-0233-MD

Valid Period : 05 Jul 2020 ~ 04 Jul 2023

Initial Date : 05 Jul 2014 Issue Date : 01 Jul 2020

Expiry Date : 04 Jul 2023

Signed for and on behalf of GCERTI President I.K.Choi









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## **EU DECLARATION OF CONFORMITY**

**1. Manufacturer:** DURICO C&T, INC. (SRN:

33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea

Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

2. Authorized Representative: DURICO IMAGING BVBA (SRN:

Villastraat 2C, 1830 Machelen, Belgium

Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

3. Products:

1) Common name: Thermal Papers for Video Printer, or Ultrasound Paper

2) Trade name: SUPER ULSTAR

3) Model: SUPER ULSTAR-1100HG

SUPER ULSTAR-1100HD

SUPER ULSTAR-1100HD Mibi

SUPER ULSTAR-1100HD Matt

SUPER ULSTAR-2100HD

SUPER ULSTAR-1100S

SUPER ULSTAR-1100S Mibi

SUPER ULSTAR-840HG

SUPER ULSTAR-840S

4) Risk Class: Class I, MDR ANNEX VIII5) Basic UDI-DI: 880917855ULSTAR3W

6) Relevant CS: N/A

7) Intended Purpose: Print media for Sony and Mitsubishi medical printer

We herewith declare that the products mentioned above meet the provisions of the EU MDR 2017/745 for medical devices.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of: DURICO C&T, INC.

Republic of Korea, April 30, 2021

Namhoon Kim

**Managing Director** 

Medical Consumables Division