

# **EU DECLARATION OF CONFORMITY**

SUPER ULSTAR

Thermal Paper for Video Printer



English(EN)	EU DECLARATION OF CONFORMITY
Bulgarian(BG)	ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ НА ЕС
Czech(CS)	EU PROHLÁŠENÍ O SHODĚ
Danish(DA)	EU-OVERENSSTEMMELSESERKLÆRING
German(DE)	EU-KONFORMITÄTSERKLÄRUNG
Greek(EL)	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ
Spanish(ES)	DECLARACIÓN DE CONFORMIDAD DE LA UE
Estonian(ET)	ELI VASTAVUSDEKLARATSIOON
Finnish(FI)	EU: N VAATIMUSTENMUKAISUUSVAKUUTUS
French(FR)	DÉCLARATION DE CONFORMITÉ UE
Irish(GA)	DEARBHÚ COMHRÉIREACHTA AN AE
Croatian(HR)	EU IZJAVA O SUKLADNOSTI
Hungarian(HU)	EU-MEGFELELŐSÉGI NYILATKOZAT
Italian(IT)	DICHIARAZIONE DI CONFORMITÀ UE
Lithuanian(LT)	ES ATITIKTIES DEKLARACIJA
Latvian(LV)	ES ATBILSTĪBAS DEKLARĀCIJA
Maltese(MT)	DIKJARAZZJONI TA 'KONFORMITÀ TAL-UE
Dutch(NL)	EU-CONFORMITEITSVERKLARING
Norwegian(NO)	EU-SAMSVARSERKLÆRING
Polish(PL)	DEKLARACJA ZGODNOŚCI UE
Portuguese(PT)	DECLARAÇÃO DE CONFORMIDADE DA UE
Romanian(RO)	DECLARAȚIA DE CONFORMITATE A UE
Slovak(SK)	VYHLÁSENIE O ZHODE EÚ
Slovenian(SL)	IZJAVA EU O SKLADNOSTI
Swedish(SV)	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE



(EN)

## EU DECLARATION OF CONFORMITY

**1. Manufacturer:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
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: BE-AR-000022105)  
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 VIII  
5) 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, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(BG)

## ДЕКЛАРАЦИЯ ЗА СЪОТВЕТВИЕ НА ЕС

**1. Производител:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Упълномощен представител:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

### **3. Продукти:**

- 1) Често срещано име: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Търговско наименование: SUPER ULSTAR  
3) Модел:

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) Клас на риска: Class I, MDR ANNEX VIII  
5) Основен UDI-DI: 880917855ULSTAR3W  
6) Съответна CS: N/A  
7) Предназначение: Носители за печат за медицински принтер Sony и Mitsubishi

С настоящото декларираме, че горепосочените продукти отговарят на разпоредбите на EU MDR 2017/745 за медицински изделия.

Настоящата декларация за съответствие се издава на единствената отговорност на производителя.

Подписано за и от името на: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(CS)

## EU PROHLÁŠENÍ O SHODĚ

**1. Výrobce:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Zplnomocněný zástupce:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. produkty:**

- 1) Běžné jméno: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Jméno výrobku: 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) Třída rizika: Class I, MDR ANNEX VIII  
5) Základní UDI-DI: 880917855ULSTAR3W  
6) Relevantní CS: N/A  
7) Zamýšlený účel: Tisková média pro lékařské tiskárny Sony a Mitsubishi

Tímto prohlašujeme, že výše uvedené produkty splňují ustanovení EU MDR 2017/745 pro zdravotnické prostředky.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

Podepsáno za a jménem: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(DA)

## EU-OVERENSSTEMMELSESERKLÆRING

**1. Fabrikant:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Autoriseret repræsentant:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkter:**

- 1) Almindeligt navn: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Handelsnavn: 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) Risikoklasse: Class I, MDR ANNEX VIII  
5) Grundlæggende UDI-DI: 880917855ULSTAR3W  
6) Relevant CS: N/A  
7) Formålet med formålet: Printmedier til medicinsk printer fra Sony og Mitsubishi

Vi erklærer hermed, at de ovennævnte produkter opfylder bestemmelserne i EU MDR 2017/745 for medicinsk udstyr.

Denne overensstemmelseserklæring udstedes under producentens eneste ansvar.

Underskrevet for og på vegne af: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(DE)

## EU-KONFORMITÄTSERKLÄRUNG

**1. Hersteller:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Bevollmächtigter Vertreter:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkte:**

- 1) Gemeinsamen Namen: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Handelsname: SUPER ULSTAR  
3) Modell:

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) Risikoklasse: Class I, MDR ANNEX VIII  
5) Grundlegende UDI-DI: 880917855ULSTAR3W  
6) Relevante CS: N/A  
7) Sinn und Zweck der Sache: Druckmedien für medizinische Drucker von Sony und Mitsubishi

Wir erklären hiermit, dass die oben genannten Produkte den Bestimmungen des EU-MDR 2017/745 für Medizinprodukte entsprechen.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

Unterzeichnet für und im Auftrag von: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(EL)

## ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

**1. Κατασκευαστής:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Εξουσιοδοτημένος αντιπρόσωπος:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Προϊόντα:**

- 1) Συνηθισμένο όνομα: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Εμπορική ονομασία: SUPER ULSTAR  
3) Μοντέλο:

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) Κατηγορία κινδύνου: Class I, MDR ANNEX VIII  
5) Βασικό UDI-DI: 880917855ULSTAR3W  
6) Σχετικό CS: N/A  
7) Προβλεπόμενος σκοπός: Μέσα εκτύπωσης για ιατρικό εκτυπωτή Sony και Mitsubishi

Δηλώνουμε ότι τα προαναφερόμενα προϊόντα πληρούν τις διατάξεις του EU MDR 2017/745 για ιατροτεχνολογικά προϊόντα.

Η παρούσα δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.

Υπογράφηκε και για λογαριασμό του: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division





(ES)

## DECLARACIÓN DE CONFORMIDAD DE LA UE

- 1. Fabricante:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461
- 2. Representante autorizado:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514
- 3. Productos:**
- 1) Nombre común: Thermal Papers for Video Printer, or Ultrasound Paper
  - 2) Nombre comercial: SUPER ULSTAR
  - 3) Modelo:

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) Clase de riesgo: Class I, MDR ANNEX VIII
  - 5) UDI-DI básico: 880917855ULSTAR3W
  - 6) CS relevante: N/A
  - 7) Finalidad prevista: Medios de impresión para impresoras médicas Sony y Mitsubishi

Por la presente declaramos que los productos mencionados anteriormente cumplen con las disposiciones del EU MDR 2017/745 para dispositivos médicos.

Esta Declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante.

Firmado para y en representación de: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(ET)

## ELI VASTAVUSDEKLARATSIOON

**1. Tootja:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Autoriseeritud esindaja:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Tooted:**

- 1) Üldnimi: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Ärinimi: SUPER ULSTAR  
3) Mudel:

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) Riskiklass: Class I, MDR ANNEX VIII  
5) Põhiline UDI-DI: 880917855ULSTAR3W  
6) Asjakohane CS: N/A  
7) Eesmärk: Sony ja Mitsubishi meditsiiniprinteri trükikandjad

Käesolevaga kinnitame, et ülalnimetatud tooted vastavad meditsiiniseadmeid käsitleva EL MDR 2017/745 sätetele.

See vastavusdeklaratsioon on välja antud ainult tootja vastutusel.

Allkirjastatud kasutaja nimel ja nimel: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(FI)

## EU: N VAATIMUSTENMUKAISUUSVAKUUTUS

**1. Valmistaja:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Valtuutettu edustaja:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Tuotteet:**

- 1) Yleinen nimi: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Kauppanimi: SUPER ULSTAR  
3) Malli:

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) Riskiluokka: Class I, MDR ANNEX VIII  
5) Perus UDI-DI: 880917855ULSTAR3W  
6) Asiaankuuluva CS: N/A  
7) Tarkoitettu tarkoitus: Tulostusvälineet Sonyn ja Mitsubishin lääketieteellisiin tulostimiin

Vakuutamme, että edellä mainitut tuotteet täyttävät lääkinnällisiä laitteita koskevan EU: n MDR 2017/745 -säännökset.

Tämä vaatimustenmukaisuusvakuutus annetaan yksin valmistajan vastuulla.

Allekirjoittanut puolesta ja puolesta: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(FR)

## DÉCLARATION DE CONFORMITÉ UE

- 1. Fabricant:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461
- 2. Représentant autorisé:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514
- 3. Produits:**
- 1) Nom commun: Thermal Papers for Video Printer, or Ultrasound Paper
  - 2) Nom commercial: SUPER ULSTAR
  - 3) Modèle:

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) Classe de risque: Class I, MDR ANNEX VIII
  - 5) UDI-DI de base: 880917855ULSTAR3W
  - 6) CS pertinent: N/A
  - 7) Objectif prévu: Moyens d'impression pour imprimantes médicales Sony et Mitsubishi

Nous déclarons par la présente que les produits mentionnés ci-dessus satisfont aux dispositions de la directive EU MDR 2017/745 pour les dispositifs médicaux.

Cette déclaration de conformité est émise sous la seule responsabilité du fabricant.

Signé pour et au nom de: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(GA)

## DEARBHÚ COMHRÉIREACHTA AN AE

- 1. Monaróir:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461
- 2. Ionadaí Údaraithe:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514
- 3. Táirgí:**
- 1) Ainm coitianta: Thermal Papers for Video Printer, or Ultrasound Paper
  - 2) Ainm trádála: SUPER ULSTAR
  - 3) Múnla:

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) Aicme Riosca: Class I, MDR ANNEX VIII
  - 5) UDI-DI bunúsach: 880917855ULSTAR3W
  - 6) CS ábhartha: N/A
  - 7) Cuspóir Beartaithe: Meáin chlóite do phrintéir leighis Sony agus Mitsubishi

Dearbhaímid leis seo go gcomhlíonann na táirgí a luaitear thuas forálacha MDR AE 2017/745 maidir le gairis leighis.

Eisítear an Dearbhú Comhréireachta seo faoi fhreagracht an mhonaróra amháin.

Sínithe ar son agus thar ceann: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(HR)

## EU IZJAVA O SUKLADNOSTI

**1. Proizvođač:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Ovlašteni predstavnik:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Proizvodi:**

- 1) Uobičajeno ime: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Trgovački naziv: 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) Klasa rizika: Class I, MDR ANNEX VIII  
5) Osnovni UDI-DI: 880917855ULSTAR3W  
6) Relevantni CS: N/A  
7) Namjera: Mediji za ispis za medicinski pisač Sony i Mitsubishi

Ovim izjavljujemo da gore navedeni proizvodi udovoljavaju odredbama EU MDR 2017/745 za medicinske uređaje.

Ova Izjava o sukladnosti izdaje se na isključivu odgovornost proizvođača.

Potpisano za i u ime: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(HU)

## EU-MEGFELELŐSÉGI NYILATKOZAT

**1. Gyártó:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Meghatalmazott képviselője:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Termékek:**

- 1) Gyakori név: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Kereskedelmi név: SUPER ULSTAR  
3) Modell:

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) Kockázati osztály: Class I, MDR ANNEX VIII  
5) Alapvető UDI-DI: 880917855ULSTAR3W  
6) Releváns CS: N/A  
7) Szándékos cél: Nyomtatási média Sony és Mitsubishi orvosi nyomtatókhoz

Ezúton kijelentjük, hogy a fent említett termékek megfelelnek az EU MDR 2017/745 orvostechnikai eszközökre vonatkozó rendelkezéseinek.

Ezt a megfelelőségi nyilatkozatot a gyártó kizárólagos felelősségével állítják ki.

Aláírta és nevében: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(IT)

## DICHIARAZIONE DI CONFORMITÀ UE

**1. Produttore:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Rappresentante autorizzato:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Prodotti:**

- 1) Nome comune: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Nome depositato: SUPER ULSTAR  
3) Modello:

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) Classe di rischio: Class I, MDR ANNEX VIII  
5) UDI-DI di base: 880917855ULSTAR3W  
6) CS pertinente: N/A  
7) Scopo previsto: Supporti di stampa per stampanti medicali Sony e Mitsubishi

Con la presente dichiariamo che i prodotti sopra menzionati soddisfano le disposizioni della EU MDR 2017/745 per i dispositivi medici.

La presente Dichiarazione di conformità viene rilasciata sotto la responsabilità esclusiva del produttore.

Firmato a nome e per conto di: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division





(LT)

## ES ATITIKTIES DEKLARACIJA

**1. Gamintojas:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Įgaliotasis atstovas:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

### **3. Produktai:**

- 1) Dažnas vardas: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Prekinis pavadinimas: SUPER ULSTAR  
3) Modelis:

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) Modelis ir UDI-DI: Class I, MDR ANNEX VIII  
5) Pagrindinis UDI-DI: 880917855ULSTAR3W  
6) Atitinkamas CS: N/A  
7) Numatytas tikslas: „Sony“ ir „Mitsubishi“ medicininio spausdintuvo spausdinimo laikmenos

Šiuo pareiškiame, kad aukščiau paminėti produktai atitinka ES MDR 2017/745 nuostatas dėl medicinos prietaisų.

Ši atitikties deklaracija yra išleista tik gamintojo atsakomybe.

Pasirašyta už ir jos vardu: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(LV)

## ES ATBILSTĪBAS DEKLARĀCIJA

**1. Ražotājs:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Pilnvarotais pārstāvis:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkti:**

- 1) Parastais nosaukums: Thermal Papers for Video Printer, or Ultrasound Paper
- 2) Tirdzniecības nosaukums: SUPER ULSTAR
- 3) Modelis:

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) Riska klase: Class I, MDR ANNEX VIII
- 5) Pamata UDI-DI: 880917855ULSTAR3W
- 6) Attiecīgais CS: N/A
- 7) Paredzētais mērķis: Drukas materiāli Sony un Mitsubishi medicīniskajam printerim

Ar šo mēs paziņojam, ka iepriekš minētie produkti atbilst ES MDR 2017/745 noteikumiem par medicīnas ierīcēm.

Šī atbilstības deklarācija ir izsniegta tikai ražotāja atbildībā.

Parakstīts par un vārdā: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(MT)

## DIKJARAZZJONI TA 'KONFORMITÀ TAL-UE

- 1. Manifattur:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461
- 2. Rappreżentant Awtorizzat:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514
- 3. Prodotti:**
- 1) Isem komuni: Thermal Papers for Video Printer, or Ultrasound Paper
  - 2) Isem kummerċjali: SUPER ULSTAR
  - 3) Mudell:

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) Klassi ta 'Riskju: Class I, MDR ANNEX VIII
  - 5) UDI-DI Bażiku: 880917855ULSTAR3W
  - 6) CS rilevanti: N/A
  - 7) Skop Maħsub: Stampa għall-istampatur mediku Sony u Mitsubishi

Aħna hawnhekk niddikjaraw li l-prodotti msemmija hawn fuq jissodisfaw id-dispożizzjonijiet tal-EU MDR 2017/745 għal apparat mediku.

Din id-Dikjarazzjoni ta 'Konformità tinħareġ taħt ir-responsabbiltà unika tal-manifattur.

Iffirmat għal u f'isem: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(NL)

## EU-CONFORMITEITSVERKLARING

**1. Fabrikant:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Bevoegde vertegenwoordiger:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Producten:**

- 1) Gemeenschappelijke naam: Thermal Papers for Video Printer, or Ultrasound Paper
- 2) Handelsnaam: 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) Risicoklasse: Class I, MDR ANNEX VIII
- 5) Basis UDI-DI: 880917855ULSTAR3W
- 6) Relevante CS: N/A
- 7) Beoogd doel: Afdrukmedia voor medische printers van Sony en Mitsubishi

Hierbij verklaren wij dat de hierboven genoemde producten voldoen aan de bepalingen van de EU MDR 2017/745 voor medische hulpmiddelen.

Deze conformiteitsverklaring wordt verstrekt onder de exclusieve verantwoordelijkheid van de fabrikant.

Ondertekend voor en namens: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(NO)

## EU-SAMSVARSERKLÆRING

**1. Produsent:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Autorisert representant:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkter:**

- 1) Vanlig navn: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Handelsnavn: SUPER ULSTAR  
3) Modell:

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) Risikoklasse: Class I, MDR ANNEX VIII  
5) Grunnleggende UDI-DI: 880917855ULSTAR3W  
6) Relevant CS: N/A  
7) Tiltenkt formål: Utskriftsmedier for medisinsk skriver fra Sony og Mitsubishi

Vi erklærer herved at produktene nevnt ovenfor oppfyller bestemmelsene i EU MDR 2017/745 for medisinsk utstyr.

Denne samsvarserklæringen utstedes på produsentens eneste ansvar.

Signert for og på vegne av: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(PL)

## DEKLARACJA ZGODNOŚCI UE

**1. Producent:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Upoważniony przedstawiciel:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkty:**

- 1) Nazwa zwyczajowa: Thermal Papers for Video Printer, or Ultrasound Paper
- 2) Nazwa handlowa: 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) Klasa ryzyka: Class I, MDR ANNEX VIII
- 5) Podstawowy UDI-DI: 880917855ULSTAR3W
- 6) Odpowiednie CS: N/A
- 7) Zamierzony cel: Nośnik do drukarek medycznych Sony i Mitsubishi

Oświadczamy, że wyżej wymienione produkty spełniają wymagania Rozporządzenia UE MDR 2017/745 dla wyrobów medycznych.

Niniejsza deklaracja zgodności wydana jest na wyłączną odpowiedzialność producenta.

Podpisano w imieniu: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(PT)

## DECLARAÇÃO DE CONFORMIDADE DA UE

**1. Fabricante:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Representante autorizado:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produtos:**

- 1) Nome comum: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Nome comercial: SUPER ULSTAR  
3) Modelo:

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) Classe de Risco: Class I, MDR ANNEX VIII  
5) UDI-DI básico: 880917855ULSTAR3W  
6) CS relevante: N/A  
7) Finalidade: Mídia de impressão para impressoras médicas Sony e Mitsubishi

Declaramos aqui que os produtos mencionados acima atendem às disposições da EU MDR 2017/745 para dispositivos médicos.

Esta Declaração de Conformidade é emitida sob a responsabilidade exclusiva do fabricante.

Assinado por e em nome de: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(RO)

## DECLARAȚIA DE CONFORMITATE A UE

**1. Producător:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Reprezentant autorizat:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produse:**

- 1) Denumirea comună: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Nume comercial: 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) Clasa de risc: Class I, MDR ANNEX VIII  
5) UDI-DI de bază: 880917855ULSTAR3W  
6) CS relevante: N/A  
7) Scopul propus: Suport de imprimare pentru imprimanta medicală Sony și Mitsubishi

Declarăm prin prezenta că produsele menționate mai sus respectă prevederile MDR UE 2017/745 pentru dispozitive medicale.

Această Declarație de conformitate este emisă sub responsabilitatea exclusivă a producătorului.

Semnat pentru și în numele: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division





(SK)

## VYHLÁSENIE O ZHODE EÚ

- 1. Výrobca:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461
- 2. Splnomocnený zástupca:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514
- 3. Produkty:**
- 1) Spoločný názov: Thermal Papers for Video Printer, or Ultrasound Paper
  - 2) Obchodné meno: 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) Trieda rizika: Class I, MDR ANNEX VIII
  - 5) Základné UDI-DI: 880917855ULSTAR3W
  - 6) Príslušné CS: N/A
  - 7) Zamýšľaný účel: Tlačové médiá pre lekárske tlačiarne Sony a Mitsubishi

Týmto vyhlasujeme, že vyššie uvedené produkty spĺňajú ustanovenia EU MDR 2017/745 pre zdravotnícke pomôcky.

Toto vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť výrobcu.

Podpísané za a v mene používateľa: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(SL)

## IZJAVA EU O SKLADNOSTI

**1. Proizvajalec:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Pooblaščen zastopnik:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Izdelki:**

- 1) Pogosto ime: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Trgovsko ime: 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) Razred tveganja: Class I, MDR ANNEX VIII  
5) Osnovni UDI-DI: 880917855ULSTAR3W  
6) Ustrezni CS: N/A  
7) Predvideni namen: Tiskalni mediji za medicinski tiskalnik Sony in Mitsubishi

Izjavljamo, da zgoraj navedeni izdelki izpolnjujejo določbe EU MDR 2017/745 za medicinske pripomočke.

Ta izjava o skladnosti je izdana na izključno odgovornost proizvajalca.

Podpisane za a v mene uporabnika: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division



(SV)

## EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

**1. Tillverkare:** DURICO C&T, INC. (SRN: KR-MF-000023740)  
33 Oedap 6-gil, Sangju-si, Gyeongbuk 37240, Republic of Korea  
Phone: +82 (0)2 525 8405 / Fax: +82 (0)2 525 7461

**2. Auktoriserad representant:** DURICO IMAGING BVBA (SRN: BE-AR-000022105)  
Villastraat 2C, 1830 Machelen, Belgium  
Phone: +32 470 632 965 / Fax: +32 (0)2 791 9514

**3. Produkter:**

- 1) Vanligt namn: Thermal Papers for Video Printer, or Ultrasound Paper  
2) Handelsnamn: SUPER ULSTAR  
3) Modell:

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) Riskklass: Class I, MDR ANNEX VIII  
5) Grundläggande UDI-DI: 880917855ULSTAR3W  
6) Relevant CS: N/A  
7) Avsedda ändamål: Utskriftsmedia för medicinsk skrivare från Sony och Mitsubishi

Vi förklarar härmed att de produkter som nämns ovan uppfyller bestämmelserna i EU MDR 2017/745 för medicintekniska produkter.

Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.

Undertecknad för och på uppdrag av: DURICO C&T, INC.

Republic of Korea, May 23, 2022

Namhoon Kim  
Executive Managing Director  
Medical Consumables Division