

EU DECLARATION OF CONFORMITY

SUPER ULSTAR

Thermal Paper for Video Printer



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Slovenian(SL)	IZJAVA EU O SKLADNOSTI
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(EN)

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
5) Basic UDI-DI: 880917855ULSTAR3W
6) Relevant CS: EN ISO 13485:2016
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



(BG)

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТВИЕ НА ЕС

1. Производител: 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. Упълномощен представител: DURICO IMAGING BVBA (SRN:)
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
- 5) Основен UDI-DI: 880917855ULSTAR3W
- 6) Съответна CS: EN ISO 13485:2016
- 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(CS)

EU PROHLÁŠENÍ O SHODĚ

1. Výrobce: 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. Zplnomocněný zástupce: DURICO IMAGING BVBA (SRN:)
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
5) Základní UDI-DI: 880917855ULSTAR3W
6) Relevantní CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(DA)

EU-OVERENSSTEMMELSESERKLÆRING

1. Fabrikant: 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. Autoriseret repræsentant: DURICO IMAGING BVBA (SRN:)
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
5) Grundlæggende UDI-DI: 880917855ULSTAR3W
6) Relevant CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(DE)

EU-KONFORMITÄTSERKLÄRUNG

1. Hersteller: 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. Bevollmächtigter Vertreter: DURICO IMAGING BVBA (SRN:)
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
5) Grundlegende UDI-DI: 880917855ULSTAR3W
6) Relevante CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(EL)

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

1. Κατασκευαστής: 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. Εξουσιοδοτημένος αντιπρόσωπος: DURICO IMAGING BVBA (SRN:)
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
5) Βασικό UDI-DI: 880917855ULSTAR3W
6) Σχετικό CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(ES)

DECLARACIÓN DE CONFORMIDAD DE LA UE

1. Fabricante: 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. Representante autorizado: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI básico: 880917855ULSTAR3W
6) CS relevante: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(ET)

ELI VASTAVUSDEKLARATSIOON

1. Tootja: 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. Autoriseeritud esindaja: DURICO IMAGING BVBA (SRN:)
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
5) Põhiline UDI-DI: 880917855ULSTAR3W
6) Asjakohane CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(FI)

EU: N VAATIMUSTENMUKAISUUSVAKUUTUS

1. Valmistaja: 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. Valtuutettu edustaja: DURICO IMAGING BVBA (SRN:)
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
5) Perus UDI-DI: 880917855ULSTAR3W
6) Asiaankuuluva CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(FR)

DÉCLARATION DE CONFORMITÉ UE

1. Fabricant: 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. Représentant autorisé: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI de base: 880917855ULSTAR3W
6) CS pertinent: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(GA)

DEARBHÚ COMHRÉIREACHTA AN AE

1. Monaróir: 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. Ionadaí Údaraithe: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI bunúsach: 880917855ULSTAR3W
6) CS ábhartha: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(HR)

EU IZJAVA O SUKLADNOSTI

1. Proizvođač: 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. Ovlašteni predstavnik: DURICO IMAGING BVBA (SRN:)
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
5) Osnovni UDI-DI: 880917855ULSTAR3W
6) Relevantni CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(HU)

EU-MEGFELELŐSÉGI NYILATKOZAT

1. Gyártó: 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. Meghatalmazott képviselője: DURICO IMAGING BVBA (SRN:)
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
5) Alapvető UDI-DI: 880917855ULSTAR3W
6) Releváns CS: EN ISO 13485:2016
7) Szándékos cél: Nyomatási 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(IT)

DICHIARAZIONE DI CONFORMITÀ UE

1. Produttore: 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. Rappresentante autorizzato: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI di base: 880917855ULSTAR3W
6) CS pertinente: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(LT)

ES ATITIKTIES DEKLARACIJA

1. Gamintojas: 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. Įgaliotasis atstovas: DURICO IMAGING BVBA (SRN:)
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
5) Pagrindinis UDI-DI: 880917855ULSTAR3W
6) Atitinkamas CS: EN ISO 13485:2016
7) Numatytas tikslas: „Sony“ ir „Mitsubishi“ medicininio spausdintuvo spausdinimo laikmenos

Šiuo pareiškime, 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(LV)

ES ATBILSTĪBAS DEKLARĀCIJA

1. Ražotājs: 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. Pilnvarotais pārstāvis: DURICO IMAGING BVBA (SRN:)
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
- 5) Pamata UDI-DI: 880917855ULSTAR3W
- 6) Attiecīgais CS: EN ISO 13485:2016
- 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(MT)

DIKJARAZZJONI TA 'KONFORMITÀ TAL-UE

1. Manifattur: 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. Rappreżentant Awtorizzat: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI Bażiku: 880917855ULSTAR3W
6) CS relevanti: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(NL)

EU-CONFORMITEITSVERKLARING

1. Fabrikant: 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. Bevoegde vertegenwoordiger: DURICO IMAGING BVBA (SRN:)
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
- 5) Basis UDI-DI: 880917855ULSTAR3W
- 6) Relevante CS: EN ISO 13485:2016
- 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(NO)

EU-SAMSVARSERKLÆRING

1. Produsent: 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. Autorisert representant: DURICO IMAGING BVBA (SRN:)
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
5) Grunnleggende UDI-DI: 880917855ULSTAR3W
6) Relevant CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(PL)

DEKLARACJA ZGODNOŚCI UE

1. Producent: 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. Upoważniony przedstawiciel: DURICO IMAGING BVBA (SRN:)
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
- 5) Podstawowy UDI-DI: 880917855ULSTAR3W
- 6) Odpowiednie CS: EN ISO 13485:2016
- 7) Zamierzony cel: Nośnik do drukarek medycznych Sony i Mitsubishi

Oświadczamy, że wyżej wymienione produkty spełniają wymagania dyrektywy 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(PT)

DECLARAÇÃO DE CONFORMIDADE DA UE

1. Fabricante: 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. Representante autorizado: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI básico: 880917855ULSTAR3W
6) CS relevante: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(RO)

DECLARAȚIA DE CONFORMITATE A UE

1. Producător: 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. Reprezentant autorizat: DURICO IMAGING BVBA (SRN:)
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
5) UDI-DI de bază: 880917855ULSTAR3W
6) CS relevante: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(SK)

VYHLÁSENIE O ZHODE EÚ

1. Výrobca: 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. Splnomocnený zástupca: DURICO IMAGING BVBA (SRN:)
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
5) Základné UDI-DI: 880917855ULSTAR3W
6) Príslušné CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(SL)

IZJAVA EU O SKLADNOSTI

1. Proizvajalec: 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. Pooblaščen zastopnik: DURICO IMAGING BVBA (SRN:)
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
5) Osnovni UDI-DI: 880917855ULSTAR3W
6) Ustrezni CS: EN ISO 13485:2016
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 uporabitelja: DURICO C&T, INC.

Republic of Korea, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division



(SV)

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

1. Tillverkare: 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. Auktoriserad representant: DURICO IMAGING BVBA (SRN:)
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
5) Grundläggande UDI-DI: 880917855ULSTAR3W
6) Relevant CS: EN ISO 13485:2016
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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division