EU DECLARATION OF CONFORMITY

SUPER ULSTAR

Thermal Paper for Video Printer

Digitally signed by Ceaicovschi Tudor
Date: 2023.08.29 15:43:38 EEST
Reason: MoldSign Signature
Location: Moldova

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
Portugese(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:)
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 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division

(BG)

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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 representacion 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, MDR ANNEX VIII
5) UDI-DI Bażiku: 880917855ULSTAR3W
6) CS relevanti: 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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, 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. Pooblaščeni 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, 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.

Podpísané za a v mene používateľa: 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, 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, April 30, 2021

Namhoon Kim
Managing Director
Medical Consumables Division

Certificate of Registration Certificate of Registration

G-CERTI *certificate*

hereby certifies that

DURICO C&T INC.

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

meets the Standard Requirements & Scope as following

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

Initial Date	**: 2014-07-05**	**Issue Date**	**: 2023-06-27**
Expiry Date	**: 2026-07-04**	**Valid Period**	**: 2023-07-05 ~ 2026-07-04**

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

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to conform to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

IAS ACCREDITED Management Systems Certification Body MSCB-113

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Certificate of Registration Certificate of Registration

G-CERTI *certificate*

hereby certifies that

DURICO C&T INC.

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

meets the Standard Requirements & Scope as following

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

Initial Date	**: 2014-07-05**	**Issue Date**	**: 2023-06-27**
Expiry Date	**: 2026-07-04**	**Valid Period**	**: 2023-07-05 ~ 2026-07-04**

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

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to conform to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

IAS ACCREDITED Management Systems Certification Body MSCB-113

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Technical Data Sheet
[ULSTAR-1100HD, High Density Grade]

Item	Specification		Evaluation Method
Physical Properties	Material	Polypropylene	
	Thickness	87 ± 5 ㎛	TAPPI T-411
	Product Size	Width 110 ± 0.1 mm Length 20 ± 0.1 m	KS B 5203
	Whiteness	88% Min	ASTM E 313
	Maximum Optical Density (Dmax)	1.70 Min	DIN 16536
	Gloss	90% Max	ASTM D 523
	Basis Weight	62 ± 4 g/㎡	TAPPI T-410
Preservation Abilities	Thermal resistance	90% Min	At 50℃, No Color Change during 1 day (Preservability of Max. Optical Density)
	Humidity Resistance	90% Min	At 40℃, 90%RH, 26 hours (Preservability of Max. Optical Density)
	Sunlight Resistance	90% Min	Below sunlight, 28℃, 50%RH, 1day, (Preservability of Max. Optical Density)

1. The data in this sheet represents average and does not constitute a warranty.
2. All the products shall be stored in a dark, cool and dry place below 30℃ / 60% RH.

Technical Data Sheet
[ULSTAR-1100HG, High Glossy Grade]

Item	Specification		Evaluation Method
Physical Properties	Material	Polypropylene	
	Thickness	87 ± 5 ㎛	TAPPI T-411
	Product Size	Width 110 ± 0.1 mm Length 18 ± 0.1 m	KS B 5203
	Whiteness	88% Min	ASTM E 313
	Maximum Optical Density (Dmax)	1.70 Min	DIN 16536
	Gloss	90% Min	ASTM D 523
	Basis Weight	62 ± 4 g/㎡	TAPPI T-410
Preservation Abilities	Thermal resistance	90% Min	At 50℃, No Color Change during 1 day (Preservability of Max. Optical Density)
	Humidity Resistance	90% Min	At 40℃, 90%RH, 26 hours (Preservability of Max. Optical Density)
	Sunlight Resistance	90% Min	Below sunlight, 28℃, 50%RH, 1day, (Preservability of Max. Optical Density)

1. The data in this sheet represents average and does not constitute a warranty.
2. All the products shall be stored in a dark, cool and dry place below 30℃ / 60% RH.

Technical Data Sheet
[ULSTAR-1100S, Standard Grade]

Item	Specification		Evaluation Method
Physical Properties	Material	Polypropylene	
	Thickness	85 ± 5 ㎛	TAPPI T-411
	Product Size	Width 110 ± 0.1 mm Length 20 ± 0.1 m	KS B 5203
	Whiteness	88% Min	ASTM E 313
	Maximum Optical Density (Dmax)	1.20 Min	DIN 16536
	Gloss	50% Min	ASTM D 523
	Basis Weight	60 ± 4 g/㎡	TAPPI T-410
Preservation Abilities	Thermal resistance	90% Min	At 50℃, No Color Change during 1 day (Preservability of Max. Optical Density)
	Humidity Resistance	90% Min	At 40℃, 90%RH, 26 hours (Preservability of Max. Optical Density)
	Sunlight Resistance	90% Min	Below sunlight, 28℃, 50%RH, 1day, (Preservability of Max. Optical Density)

1. The data in this sheet represents average and does not constitute a warranty.
2. All the products shall be stored in a dark, cool and dry place below 30℃ / 60% RH.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer:

Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization:
Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:
Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Sphygmomanometers, Disposable Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets, Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use,Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes(Standard & Reinforced), Disposable Oxygen Mask, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in sterilization Packing

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-08-07

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer:

Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ