



EU Declaration of Conformity

The EC Regulation covered by this Declaration is (EU) MDR 2017/745. This Declaration of Conformity is issued under the sole responsibility of International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Manufacturer: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Authorized Representative: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florence, Italy

The Products Covered by this Declaration are the medical devices known as:

SteriBest Instrument Trays, Model Numbers and Basic UDI-DI:

Model Number	Basic UDI-DI	Model Number	Basic UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest Instrument Trays are designed to encase non-lumened instruments during sterilization.

This medical device's risk class is Class I (Regulation 2017/745, Annex VIII, Rule 1).

The device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Signed by: _____

Name: Ben Haak

Title: CEO

Signed at 9207 Ivanhoe, Schiller Park, IL 60176

Date: April 20, 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Dichiarazione di Conformità – EU

La norma Europea di riferimento per questa Dichiarazione è la MDR-EU 2017/745. Questa Dichiarazione di Conformità viene rilasciata sotto la sola responsabilità di International Surgical Products, Inc. e di DBA RICA Surgical Products, Inc.

Fabbricante: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Rappresentante Autorizzato: B. M. Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Firenze, Italia

I Prodotti coperti da questa Dichiarazione di Conformità sono Dispositivi Medici conosciuti come:

SteriBest Instrument Trays, con i seguenti Codici di Catalogo e Basic UDI-DI:

Codice di Catalogo	Basic UDI-DI	Codice di Catalogo	Basic UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Gli SteriBest Instrument Trays sono concepiti per contenere e proteggere strumenti chirurgici NON CANNULATI durante sterilizzazione.

La Classe di Rischio di questi Dispositivi Medici è la Classe I (Norma 2017/745, Allegato VIII, Regola 1)

I Dispositivi elencati nella presente Dichiarazione sono Conformi alla Norma (EU) MDR 2017/745

Firma: _____

Nome: Ben Haak

Titolo: CEO

Firmato a: 9207 Ivanhoe, Schiller Park, IL 60176

Data: 20 Aprile, 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



ЕС декларация за съответствие

Регламентът на ЕО, обхванат от тази декларация, е (ЕС) MDR 2017/745. Тази декларация за съответствие е издадена под изключителната отговорност на International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Производител: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Упълномощен представител: В. М. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florence, Italy

Продуктите, обхванати от тази декларация, са медицинските изделия, известни като:

Поставки за инструменти SteriBest, номер на модел и базов UDI-DI:

Номер на модела	Базов UDI-DI	Номер на модела	Базов UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Тавите за инструменти SteriBest са предназначени за поставяне на инструменти без осветление по време на стерилизация.

Класът на риск на това медицинско изделие е клас I (Регламент 2017/745, приложение VIII, правило 1).

Устройството, обхванато от настоящата декларация на ЕС, е в съответствие с (ЕС) MDR 2017/745.

Подписал: _____

Име: Бен Хаак

Длъжност: Главен изпълнителен директор

Подписано на адрес: 9207 Ivanhoe, Schiller Park, IL 60176

Дата: 20 април 2021 г.

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EU prohlášení o shodě

Nařízení ES, kterým se řídí toto prohlášení: (EU) 2017/745 o zdravotnických prostředcích. Toto prohlášení o shodě se vydává na výhradní odpovědnost společnosti International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Výrobce: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176, Spojené státy

Autorizovaný zástupce: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florencie, Itálie

Toto prohlášení se týká zdravotnických prostředků známých pod označením:

Příhrádky na nástroje SteriBest, čísla modelů a základní UDI-DI:

Číslo modelu	Základní UDI-DI	Číslo modelu	Základní UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Podnosy na nástroje SteriBest jsou navrženy tak, aby během sterilizace obalily nástroje bez dutin.

Tento zdravotnický prostředek spadá do třídy rizika I (nařízení 2017/745, příloha VIII, pravidlo 1).

Prostředek, jehož se týká toto prohlášení, je ve shodě s nařízením (EU) 2017/745 o zdravotnických prostředcích.

Podepsán(a): _____

Jméno: Ben Haak

Pozice: CEO

Podepsáno na adrese 9207 Ivanhoe, Schiller Park, IL 60176

Datum: 20. dubna 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176

DA



EU-overensstemmelseserklæring

EF-forordningen, der er omfattet af denne erklæring, er (EU) MDR 2017/745. Denne overensstemmelseserklæring udstedes under ansvar af International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Producent: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Autoriseret repræsentant: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Firenze, Italien

De produkter, der er omfattet af denne erklæring, er medicinsk udstyr kendt som:

SteriBest instrumentbakker, modelnumre og grundlæggende UDI-DI:

Modelnummer	Grundlæggende UDI-DI	Modelnummer	Grundlæggende UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest instrumentbakker er designet til at indkapsle instrumenter uden lumen under sterilisering.

Dette medicinske udstyrs risikoklasse er klasse I (forordning 2017/745, bilag VIII, regel 1).

Enheden, der er omfattet af denne EU -erklæring, er i overensstemmelse med (EU) MDR 2017/745.

Signeret af: _____

Navn: Ben Haak

Titel: CEO

Signeret på 9207 Ivanhoe, Schiller Park, IL 60176

Dato: 20. april 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EU-Konformitätserklärung

Die von dieser Erklärung erfasste EG-Verordnung ist (EU) MDR 2017/745. Diese Konformitätserklärung wird unter der alleinigen Verantwortung von International Surgical Products, Inc. und DBA RICA Surgical Products, Inc. ausgestellt.

Hersteller: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Autorisierter Vertreter: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florenz, Italien

Die von dieser Erklärung abgedeckten Produkte sind die Medizinprodukte mit den folgenden Bezeichnungen:

SteriBest-Instrumentenschalen, Modellnummern und Basis UDI-DI:

Modellnummer	Basis UDI-DI	Modellnummer	Basis UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest-Instrumentenschalen sind so konzipiert, dass sie nicht-lumige Instrumente während der Sterilisation umschließen.

Die Risikoklasse dieses Medizinprodukts ist Klasse I (Verordnung 2017/745, Anhang VIII, Regel 1).

Das von dieser EU-Erklärung erfasste Gerät ist konform mit der Verordnung (EU) MDR 2017/745.

Unterzeichnet von: _____

Name: Ben Haak

Titel: Geschäftsführer

Unterzeichnet bei 9207 Ivanhoe, Schiller Park, IL 60176

Datum: 20. April 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Δήλωση συμμόρφωσης ΕΕ

Ο κανονισμός ΕΚ που καλύπτεται από την παρούσα Δήλωση είναι ο MDR (ΕΕ) 2017/745 (Κανονισμός για τα ιατροτεχνολογικά προϊόντα). Η παρούσα Δήλωση Συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη της International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Κατασκευαστής: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 ΗΠΑ

Εξουσιοδοτημένος Αντιπρόσωπος: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Φλωρεντία, Ιταλία

Τα προϊόντα που καλύπτονται από αυτήν τη δήλωση είναι οι ιατρικές συσκευές:

Δίσκοι εργαλείων SteriBest, με κωδικούς μοντέλων και βασικά UDI-DI:

Κωδικός μοντέλου	Βασικό UDI-DI	Κωδικός μοντέλου	Βασικό UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Οι δίσκοι SteriBest έχουν σχεδιαστεί για την εναπόθεση μη σωληνωτών εργαλείων κατά τη διάρκεια της αποστείρωσης.

Η κατηγορία κινδύνου αυτής της ιατρικής συσκευής είναι η Κατηγορία Ι (Κανονισμός 2017/745, Παράρτημα VIII, Κανόνας 1).

Η συσκευή που καλύπτεται από την παρούσα δήλωση ΕΕ είναι σύμφωνη με τον Κανονισμό (ΕΕ) MDR 2017/745.

Υπογράφηκε από: _____

Όνομα: Ben Haak

Τίτλος: Διευθύνων Σύμβουλος

Υπογράφηκε στο 9207 Ivanhoe, Schiller Park, IL 60176

Ημερομηνία: 20 Απριλίου 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Declaración de conformidad CE

El Reglamento de la CE al que se refiere esta Declaración es el (UE) MDR 2017/745. Esta Declaración de Conformidad se realiza bajo la única responsabilidad de International Surgical Products, Inc. DBA RICA Surgical Products, Inc.

Fabricante: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 EE. UU.

Representante autorizado: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florencia, Italia

Los Productos cubiertos por esta Declaración son los dispositivos médicos conocidos como:

Bandejas para instrumentos SteriBest, números de modelo y UDI-DI básico:

Número de modelo	UDI-DI básico	Número de modelo	UDI-DI básico
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Las bandejas para instrumentos de SteriBest se han diseñado para albergar instrumentos no huecos durante la esterilización.

La clase de riesgo de este dispositivo médico es Clase I (Reglamento 2017/745, nexo VIII, norma 1).

El dispositivo cubierto por la presente declaración de la CE está en conformidad con el (UE) MDR 2017/745.

Firmado por: _____

Nombre: Ben Haak
Cargo: Director ejecutivo
Firmado en 9207 Ivanhoe, Schiller Park, IL 60176
Fecha: 20 de abril de 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176

ET



ELi vastavusdeklaratsioon

Käesolev deklaratsioon on vastavuses ELi meditsiiniseadmete määrusega (EL) 2017/745. Selle vastavusdeklaratsiooni eest on ainuvastutav International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Tootja: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Volitatud esindaja: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Firenze, Itaalia

Käesolev deklaratsioon hõlmab järgmise nime all tuntud meditsiiniseadmeid:

SteriBest instrumentialused, mudelinumbrid ja põhi-UDI-DI:

Mudeli number	Põhi-UDI-DI	Mudeli number	Põhi-UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest instrumentialused on mõeldud õõnsuseta instrumentide hoidmiseks steriliseerimise ajal.

Selle meditsiiniseadme riskiklass on I klass (määrus 2017/745, VIII lisa, reegel 1).

Käesoleva ELi deklaratsiooniga hõlmatud seade on vastavuses ELi meditsiiniseadmete määrusega (EL) 2017/745.

Allkirjastanud: _____

Nimi: Ben Haak

Ametinimetus: tegevjuht

Allkirjastatud aadressil 9207 Ivanhoe Street, Schiller Park, IL 60176 USA

Kuupäev: 20. aprill 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EU-vaatimustenmukaisuusvakuutus

Tämän julistuksen kattama EY -asetus on (EU) MDR 2017/745. Tämä vaatimustenmukaisuusvakuutus on annettu International Surgical Products, Inc., DBA RICA Surgical Products, Inc. -yhtiön yksinomaisella vastuulla.

Valmistaja: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Valtuutettu edustaja: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Firenze, Italia

Tämän julistuksen kattamat tuotteet ovat lääkinällisiä laitteita, jotka tunnetaan nimellä:

SteriBest-instrumenttilokerot, mallinumero ja perus UDI-DI:

Mallinumero	Perus UDI-DI	Mallinumero	Perus UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest-instrumenttilokerot on suunniteltu lumenittomien instrumenttien koteloksi steriloinnin aikana.

Tämän lääkinällisen laitteen riskiluokka on luokka I (asetus 2017/745, liite VIII, sääntö 1).

Nykyisen EU-vakuutuksen kattama laite on (EU) MDR 2017/745 -standardin mukainen.

Allekirjoittanut: _____

Nimi: Ben Haak

Titteli: toimitusjohtaja

Allekirjoitettu osoitteessa 9207 Ivanhoe, Schiller Park, IL 60176

Päivämäärä: 20. huhtikuuta 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Déclaration de conformité UE

La réglementation CE couverte par cette déclaration est la suivante : (UE) MDR 2017/745. Cette déclaration de conformité est émise sous la seule responsabilité d'International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Fabricant : International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 États-Unis

Représentant agréé : BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Florence, Italy

Les produits couverts par cette déclaration sont les dispositifs médicaux ainsi désignés :

Plateaux à instruments SteriBest, numéros de modèle et UDI-DI de base :

Numéro de modèle	UDI-DI de base	Numéro de modèle	UDI-DI de base
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Les plateaux à instruments SteriBest sont conçus pour accueillir les instruments sans lumière pendant la stérilisation.

La classe de risque de ce dispositif médical est la classe I (Règlement 2017/745, Annexe VIII, Règle 1).

L'appareil couvert par la présente déclaration UE est conforme au règlement (UE) MDR 2017/745.

Signé par : _____

Nom : Ben Haak

Fonction : PDG

Signé au 9207 Ivanhoe, Schiller Park, IL 60176

Date : 20 avril 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176

GA



Dearbhú Comhréireachta AE

Is é (AE) MDR 2017/745 an Rialachán CE a chlúdaítear sa Dearbhú seo. Eisítear an Dearbhú Comhréireachta seo faoi fhreagracht idirnáisiúnta International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Monaróir: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Ionadaí Údaraithe: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Flórans, an Iodáil

Is iad na Táirgí a Clúdaítear sa Dearbhú seo na feistí leighis ar a dtugtar:

Tráidirí Uirlisí SteriBest, Uimhreacha Múnla agus UDI-DI Bunúsach:

Uimhir Mhúnla	UDI-DI bunúsach	Uimhir Mhúnla	UDI-DI bunúsach
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Dearadh Tráidirí Uirlisí SteriBest chun uirlisí neamh-lúmain a chásáil le linn steirilithe.

Is é Aicme I aicme riosca na feiste leighis seo (Rialachán 2017/745, Iarscríbhinn VIII, Riail 1).

Tá an fheiste a chlúdaítear sa dearbhú reatha AE i gcomhréir le MDR (AE) 2017/745.

Síniú: _____

Ainm: Ben Haak

Teideal: POF

Sínte ag 9207 Ivanhoe, Schiller Park, IL 60176

Dáta: 20 Aibreán, 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176

HR



EU Izjava o sukladnosti

Uredba (EZ) na koju se odnosi ova Izjava jest Uredba (EU) 2017/745 o medicinskim proizvodima. Ova Izjava o sukladnosti izdana je pod isključivom odgovornošću tvrtke International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Proizvođač: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 SAD

Ovlašteni zastupnik: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Firenca, Italija

Proizvodi na koje se odnosi ova Izjava medicinski su proizvodi pod nazivom:

Pladnjevi za instrumente SteriBest, brojevi modela i osnovni jedinstveni identifikator (UDI-DI):

Broj modela	Osnovni jedinstveni identifikator (UDI-DI)	Broj modela	Osnovni jedinstveni identifikator (UDI-DI)
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Pladnjevi za instrumente marke SteriBest dizajnirani su za odlaganje instrumenata bez šupljina tijekom sterilizacije.

Klasa rizika ovog medicinskog proizvoda je Klasa I (Uredba 2017/745, Prilog VIII, Pravilo 1).

Uređaj na koji se odnosi ova EU izjava u skladu je s Uredbom (EU) 2017/745 o medicinskim proizvodima.

Potpisuje: _____

Ime: Ben Haak
Radno mjesto: izvršni direktor
Mjesto potpisivanja: 9207 Ivanhoe, Schiller Park, IL 60176
Datum: 20. travnja 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EU-megfelelőségi nyilatkozat

A jelen nyilatkozatot az orvostechnikai eszközökről szóló (EU) 2017/745 uniós rendelet alapján állították ki. A jelen megfelelési nyilatkozat kiadása az International Surgical Products, Inc., DBA RICA Surgical Products, Inc. kizárólagos felelőssége mellett történik.

Gyártó: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Meghatalmazott képviselő: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Firenze, Olaszország

A jelen nyilatkozat az alábbi neveken ismert orvostechnikai eszközökre vonatkozik:
SteriBest műszertálcák, modellszámok és alapvető UDI-DI:

Modellszám	Alapvető UDI-DI	Modellszám	Alapvető UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

A SteriBest műszertálcákat úgy tervezték, hogy sterilizálás során nem üreges műszereket helyezzenek rájuk.

Ez az orvostechnikai eszköz az I-es kockázati osztályba tartozik (2017/745 rendelet, VIII. melléklet, 1. szabály).

A jelen EU-megfelelőségi nyilatkozat tárgyát képező eszköz összhangban van az orvostechnikai eszközökről szóló (EU) 2017/745 rendelettel.

Aláírás: _____

Név: Ben Haak

Beosztás: vezérigazgató

Aláírás helye: 9207 Ivanhoe, Schiller Park, IL 60176

Dátuma: 2021. április 20.

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



ES atitikties deklaracija

EB reglamentas, pagal kurį teikiama ši deklaracija, yra (ES) MDR 2017/745. Ši atitikties deklaracija yra išleista atsakomybę už ją prisiimant tik International Surgical Products, Inc., vykdančiai veiklą kaip RICA Surgical Products, Inc.

Gamintojas: International Surgical Products, Inc., vykdanči veiklą kaip RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 JAV

Ilgaliotasis atstovas: B. M. Sanitas S.R.L.

Via Caduti di Cefalonia 90, 50127 Florencija, Italija

Gaminiai, kuriems taikoma ši deklaracija, yra medicinos prietaisai, žinomi kaip:

SteriBest instrumentų dėklai, modelių numeriai ir pagrindiniai UDI-DI:

Modelio numeris	Pagrindinis UDI-DI	Modelio numeris	Pagrindinis UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest instrumentų dėklai yra suprojektuoti taip, kad sterilizavimo metu apgautų ertmių neturinčius instrumentus.

Šio medicinos prietaiso rizikos klasė yra I klasė (2017/745 reglamento VIII priedo 1 taisyklė).

Prietaisas, kuriam taikoma ši ES deklaracija, atitinka (ES) MDR 2017/745.

Pasirašė: _____

Vardas ir pavardė: Ben Haak

Pareigos: generalinis direktorius

Pasirašymo vieta: 9207 Ivanhoe, Schiller Park, IL 60176, JAV

Data: 2021 m. balandžio 20 d.

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EK atbilstības deklarācija

EK regula, uz kuru attiecas šī deklarācija, ir (ES) MDR 2017/745. Par šīs atbilstības deklarācijas izdošanu ir atbildīgs tikai International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Ražotājs: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 ASV

Pilnvarotais pārstāvis: BM Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florence, Itālija

Produkti, uz kuriem attiecas šī deklarācija, ir šādas medicīnas ierīces:

SteriBest instrumentu paplātes (modeļu numuri un pamata UDI-DI):

Modeļa numurs	Pamata UDI-DI	Modeļa numurs	Pamata UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest instrumentu paplātes ir paredzētas lūmenu nesaturošu instrumentu sterilizācijai.

Šīs medicīnas ierīces riska klase ir I klase (Regula 2017/745, VIII pielikums, 1. noteikums).

Ierīce, uz kuru attiecas šī ES deklarācija, atbilst (ES) MDR 2017/745.

Parakstījis: _____

Vārds: Bens Hāks (Ben Haak)

Amats: izpilddirektors

Parakstīts 9207 Ivanhoe, Schiller Park, IL 60176

Datums: 2021. gada 20. aprīlis

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176

MT



Dikjarazzjoni ta' Konformità tal-UE

Ir-Regolament KE li did-dikjarazzjoni taqa' tahtu huwa (UE) MDR 2017/745. Din id-Dikjarazzjoni ta' Konformità qed tinhareg biss għar-responsabbiltà unika ta' International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Manifattur: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Rappreżentant Awtorizzat: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Firenze, I-Italja

Il-Prodotti Li Jaqgħu taht did-Dikjarazzjoni huma t-tagħmir mediku magħruf bħala:

SteriBest Instrument Trays, Numri tal-Mudelli u UDI-DI Bażiku:

Numru tal-Mudell	UDI-DI Bażiku	Numru tal-Mudell	UDI-DI Bażiku
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

L-iSteriBest Instrument Trays huma mfasla biex jinżammu fihom l-istrumenti mingħajr lumen waqt li dawn ikunu qed jiġu sterilizzati.

Il-kategorija tar-riskju ta' dat-tagħmir mediku hija Klassi I (Regolament 2017/745, Anness VIII, Regola numru 1).

It-tagħmir li jaqa' taht did-dikjarazzjoni tal-UE huwa skont (UE) MDR 2017/745.

Iffirmat minn: _____

Name: Ben Haak

Titlu: CEO

Iffirmat għewwa 9207 Ivanhoe, Schiller Park, IL 60176

Data: 20 ta' April 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EG-conformiteitsverklaring

Deze verklaring valt onder de EG-verordening (EU) MDR 2017/745. Deze conformiteitsverklaring wordt uitgegeven onder de exclusieve verantwoordelijkheid van International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Fabrikant: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Geautoriseerde vertegenwoordiger: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Firenze, Italië

De producten die onder deze verklaring vallen, zijn de medische hulpmiddelen die bekend staan als:

SteriBest Instrumentenschalen, modelnummers en Basic UDI-DI:

Modelnummer	Basic UDI-DI	Modelnummer	Basic UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest Instrumentenschalen zijn ontworpen voor het steriliseren van instrumenten zonder lumen.

De risicoklasse van dit medische hulpmiddel is Klasse I (Verordening 2017/745, Bijlage VIII, Regel 1).

Het apparaat waarop deze EU-verklaring betrekking heeft, is in overeenstemming met de (EU) MDR 2017/745.

Ondertekend door: _____

Naam: Ben Haak

Titel: CEO

Ondertekend te 9207 Ivanhoe, Schiller Park, IL 60176

Datum: 20 april 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Deklaracja zgodności UE

Rozporządzenie WE objęte niniejszą deklaracją to (UE) MDR 2017/745. Niniejsza deklaracja zgodności została wydana na wyłączną odpowiedzialność International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Producent: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Autoryzowany przedstawiciel: B.M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florencja, Włochy

Produkty objęte niniejszą deklaracją to wyroby medyczne znane jako:

Tace na narzędzia SteriBest, numery modeli i podstawowe UDI-DI:

Numer modelu	Podstawowy UDI-DI		Numer modelu	Podstawowy UDI-DI
CP1038D1	00850017474048		CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277		CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284		CP614	00850017474222
CP1038D1-SB	00850017474055		CP614-DK-1	00850017474352
CP1038D2	00850017474062		CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079		CP614-DK-3	00850017474376
CP1038S	00850017474192		CP614-SB	00850017474130
CP1038S-SB	00850017474086		CP634	00850017474246
CP471D1	00850017474093		CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291		CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307		CP778	00850017474260
CP471D1-SB	00850017474109		CP778-DK-1	00850017474383
CP471S	00850017474116		CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314		CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321		CP778-SB	00850017474154
CP471S-DK-4	00850017474338		CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178		CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208		CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239		CP614-DK-SB	00850017474437
CP634-NM	00850017474253		CP778-DK-SB	00850017474444
E7407	00850017474451		E7411	00850017474468
E7406	00850017474475		E7409	00850017474482

Tace na narzędzia SteriBest są przeznaczone do umieszczania narzędzi bezkanałowych podczas sterylizacji.

Klasa ryzyka tego wyrobu medycznego to Klasa I (Rozporządzenie 2017/745, Załącznik VIII, Zasada 1).

Urządzenie objęte niniejszą deklaracją UE jest zgodne z (UE) MDR 2017/745.

Podpisano: _____

Imię i nazwisko: Ben Haak
Stanowisko: Dyrektor Naczelny (CEO)
Podpisano w 9207 Ivanhoe, Schiller Park, IL 60176
Data: 20 kwietnia 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Declaração de conformidade CE

O regulamento CE coberto por esta declaração é (UE) MDR 2017/745. Esta Declaração de Conformidade é emitida sob a responsabilidade exclusiva da International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Fabricante: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 EUA

Representante Autorizado: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Florença, Itália

Os produtos abrangidos por esta declaração são os dispositivos médicos conhecidos como:

Bandejas de instrumentos SteriBest, números de modelo e UDI-DI básico:

Número do modelo	UDI-DI básico		Número do modelo	UDI-DI básico
CP1038D1	00850017474048		CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277		CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284		CP614	00850017474222
CP1038D1-SB	00850017474055		CP614-DK-1	00850017474352
CP1038D2	00850017474062		CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079		CP614-DK-3	00850017474376
CP1038S	00850017474192		CP614-SB	00850017474130
CP1038S-SB	00850017474086		CP634	00850017474246
CP471D1	00850017474093		CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291		CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307		CP778	00850017474260
CP471D1-SB	00850017474109		CP778-DK-1	00850017474383
CP471S	00850017474116		CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314		CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321		CP778-SB	00850017474154
CP471S-DK-4	00850017474338		CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178		CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208		CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239		CP614-DK-SB	00850017474437
CP634-NM	00850017474253		CP778-DK-SB	00850017474444
E7407	00850017474451		E7411	00850017474468
E7406	00850017474475		E7409	00850017474482

As bandejas de instrumentos SteriBest foram concebidas para envolver instrumentos sem lúmen durante a esterilização.

A classe de risco deste dispositivo médico é Classe I (Regulamento 2017/745, Anexo VIII, Regra 1).

O dispositivo coberto pela presente declaração da UE está em conformidade com o (UE) MDR 2017/745.

Assinado por: _____

Nome: Ben Haak

Cargo: CEO

Assinado em 9207 Ivanhoe, Schiller Park, IL 60176

20 de abril de 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



DECLARAȚIA DE CONFORMITATE UE

Regulamentul CE acoperit de această declarație este (UE) MDR 2017/745. Această declarație de conformitate este emisă sub responsabilitatea exclusivă a International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Producător: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Reprezentant autorizat: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Florența, Italia

Produsele acoperite de această declarație sunt dispozitivele medicale cunoscute ca:

SteriBest tăvi de instrumente, numere de model și UDI-DI de bază:

Nr. modelului	UDI-DI de bază	Nr. modelului	UDI-DI de bază
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Tăvile de instrumente SteriBest sunt proiectate pentru a încadra instrumentele neluminate în timpul sterilizării.

Clasa de risc a acestui dispozitiv medical este clasa I (Regulamentul 2017/745, anexa VIII, regula 1).

Dispozitivul acoperit de prezenta declarație UE este în conformitate cu (UE) MDR 2017/745.

Semnat de către: _____

Nume: Ben Haak

Titlu: CEO

Semnat la 9207 Ivanhoe, Schiller Park, IL 60176

Data: 20 aprilie 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Vyhlásenie o zhode EÚ

Nariadenie ES, na ktoré sa vzťahuje toto vyhlásenie, je (EÚ) MDR 2017/745. Toto vyhlásenie o zhode je vydané na výhradnú zodpovednosť spoločností International Surgical Products, Inc. a DBA RICA Surgical Products, Inc.

Výrobca: International Surgical Products, Inc. a DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Splnomocnený zástupca: BM Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Florencia, Taliansko

Výrobky, na ktoré sa vzťahuje toto vyhlásenie, sú zdravotnícke pomôcky známe ako:

Podnosy na nástroje SteriBest, čísla modelov a základné UDI-DI:

Číslo modelu	Základné UDI-DI	Číslo modelu	Základné UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Podnosy na nástroje SteriBest sú navrhnuté tak, aby počas sterilizácie plnili funkciu puzdra na neosvetlené nástroje.

Táto zdravotnícka pomôcka patrí do triedy rizika I (nariadenie 2017/745, príloha VIII, pravidlo 1).

Zariadenie, na ktoré sa vzťahuje toto vyhlásenie EÚ, je v súlade s nariadením (EÚ) MDR 2017/745.

Podpísal(-a): _____

Meno: Ben Haak

Funkcia: Výkonný riaditeľ

Miesto podpisu: 9207 Ivanhoe, Schiller Park, IL 60176

Dátum: 20. apríla 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



Izjava EU o skladnosti

Uredba ES, zajeta v tej deklaraciji, je (EU) MDR 2017/745. Ta izjava o skladnosti je izdana na izključno odgovornost podjetja International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Proizvajalec: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Pooblaščen zastopnik: B. M. Sanitas S.R.L.
Via Caduti di Cefalonia 90, 50127 Firenze, Italija

Izdelki, zajeti v tej deklaraciji, so medicinski pripomočki z nazivom:

SteriBest pladnji za instrumente, številke modelov in osnovni UDI-DI:

Številka modela	Osnovni UDI-DI	Številka modela	Osnovni UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

Pladnji za instrumente SteriBest so zasnovani tako, da med sterilizacijo obložijo instrumente brez lumnov.

Razred tveganja tega medicinskega pripomočka je razred I (Uredba 2017/745, Priloga VIII, Pravilo 1).

Naprava, zajeta v tej izjavi EU, je v skladu z (EU) MDR 2017/745.

Podpis: _____

Ime: Ben Haak

Naziv: Generalni direktor

Podpisano na naslovu 9207 Ivanhoe, Schiller Park, IL 60176

Datum: 20. april, 2021

RICA Surgical Products, Inc.

Phone: 1-800-889-3128 | Fax: 1-847-671-5690 | www.ricasurgical.com

9207 Ivanhoe Street | Schiller Park, IL 60176



EU-försäkran om överensstämmelse

EG-förordningen som omfattas av denna deklaration är (EU) MDR 2017/745. Denna försäkran om överensstämmelse utfärdas på eget ansvar av International Surgical Products, Inc., DBA RICA Surgical Products, Inc.

Tillverkare: International Surgical Products, Inc., DBA RICA Surgical Products, Inc.
9207 Ivanhoe, Schiller Park, IL 60176 USA

Auktoriserad representant: BM Sanitas SRL
Via Caduti di Cefalonia 90, 50127 Florens, Italien

De produkter som omfattas av denna deklaration är medicintekniska produkter som kallas:

SteriBest instrumentbrickor, modellnummer och grundläggande UDI-DI:

Modellnummer	Grundläggande UDI-DI	Modellnummer	Grundläggande UDI-DI
CP1038D1	00850017474048	CP471S-DK-5	00850017474345
CP1038D1-P-1S/L	00850017474277	CP471S-SB	00850017474123
CP1038D1-P-3S/L	00850017474284	CP614	00850017474222
CP1038D1-SB	00850017474055	CP614-DK-1	00850017474352
CP1038D2	00850017474062	CP614-DK-2	00850017474369
CP1038D2-SB	00850017474079	CP614-DK-3	00850017474376
CP1038S	00850017474192	CP614-SB	00850017474130
CP1038S-SB	00850017474086	CP634	00850017474246
CP471D1	00850017474093	CP634-DK-5	00850017474420
CP471D1-P-1S/L	00850017474291	CP634-SB	00850017474147
CP471D1-P-3S/L	00850017474307	CP778	00850017474260
CP471D1-SB	00850017474109	CP778-DK-1	00850017474383
CP471S	00850017474116	CP778-DK-2	00850017474390
CP471S-DK-2	00850017474314	CP778-DK-3	00850017474406
CP471S-DK-3	00850017474321	CP778-SB	00850017474154
CP471S-DK-4	00850017474338	CP1038D1-NM	00850017474161
CP1038D1-NM-SB	00850017474178	CP1038D2-NM	00850017474185
CP1038S-NM	00850017474208	CP1038S-NM-SB	00850017474215
CP614-NM	00850017474239	CP614-DK-SB	00850017474437
CP634-NM	00850017474253	CP778-DK-SB	00850017474444
E7407	00850017474451	E7411	00850017474468
E7406	00850017474475	E7409	00850017474482

SteriBest instrumentbrickor är utformade för att omsluta icke-luminerade instrument under sterilisering.

Denna medicintekniska produkts riskklass är klass I (förordning 2017/745, bilaga VIII, regel 1).

Enheten som omfattas av denna EU-deklaration överensstämmer med (EU) MDR 2017/745.

Undertecknat av: _____

Namn: Ben Haak

Titel: VD

Signerad på 9207 Ivanhoe, Schiller Park, IL 60176

Datum: 20 april 2021

RICA Surgical Products, Inc.

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