2025-0163

Centro Solicitante: HOSPITEN RAMBLA

SAP	PROVEEDOR DENOMINACION	RFA	PREST	PROPUESTA INCLUSION MEDICAL CANARIA COSTE CAJA	UNIDAD
828358	CONECTOR RECTO 22MM-22F	1963	25	46,25 €	1,85 €

VIGENCIA TARIFA 31/12/2025
PRECIOS PUESTOS EN LA PUERTA DEL HOSPITAL.

A rellenar por el centro,Marcar con una X si el Material Sanitario es NO facturable.

	ADESLAS	DKV	SANITAS		
Amb.					
Hosp.					

El Centro Hospitalario se responsabilizará que dicho material sea facturado al paciente y/o Entidad Aseguradora Pública o Privada,con especial atención a pacientes de Entidades Aseguradoras las cuales requieran consentimiento y autorización previa antes de su uso o aplicación.
Si el paciente es asegurado de entidades quienes tienen acuerdos con proveedores,previamente la Dirección o Administración del Hospital deberá verificar las marcas y/o proveedores homologados por la Entidad.
En caso que el paciente pertenezca a Entidades Aseguradora Públicas o Privadas con quines tengamos "Tarifa de Prestación Cerrada",antes de dar conformidad la Dirección del hospital deberá analizar el coste del material junto con la tarifa de prestación.

GRUPO:VA (Material Diálisis).
CLASE: VA01 (Ventiloterapia y anestesia).
CARACTERISTICAS: VA0108 (Conectores).

Informe y/o Gestión realizada por:
Gara Fernandez Hernandez

Fdo.....

31/01/2025

(14)

MODELO 1. ADMISIÓN DE NUEVOS MATERIALES

PROPUESTA DE NUEVO MATERIAL HOSPITALARIO PARA SU INCLUSIÓN EN LA GUÍA HOSPITALARIA DE HOSPITEN

Rambla de Santa Cruz, 115
38001 Santa Cruz de Tenerife
Islas Canarias. España
T +34 922 291 600
Consultas +34 922 634 240
rambla@hospiten.com

1. **Nombre y referencia material:** CONECTOR RECTO 22M - 22F CON CONECTOR 6MM
2. **Nombre comercial:** CONNECTOR 22M 22F + 6MM STEM
3. **Laboratorio:** INTERSURGICAL
4. **Presentación:** Envase individual esterilizado
5. **Aplicación:** CONECTOR PARA OXIGENOTERAPIA EN LA TUBULADURA DE VMNI O CPAP, PARA AÑADIR OXÍGENO A PACIENTE VENTILADO
6. **Descripción del producto:** CONECTOR PARA OXIGENOTERAPIA EN LA TUBULADURA DE VMNI O CPAP
7. **Reséñese la acción diagnóstica/terapéutica principal y el uso terapéutico del material que justifique su inclusión:** Se utiliza para añadir oxígeno a pacients ventidados con CPAP o BiPAP
8. **Materiales de uso actual en Hospiten código SAP:** NO HAY. 8B835X conector recto 22m-22m
9. **Razones clínicas por las cuales este material es superior a los citados anteriormente:** NO HAY.
10. **¿Qué materiales considera usted podrían retirarse de la Guía reseñados anteriormente?** NINGUNO

A rellenar por el centro. Marcar con una x si el **MATERIAL SANITARIO** es **NO** facturable.

	Adeslas	DKV	Sanitas			
Amb	☐	☐	☐	☐	☐	☐
Hosp	☐	☐	☐	☐	☐	☐

FECHA:

DR./SERVICIO SOLICITANTE

NEUMOLOGÍA

Fdo.: Dr. Magdalena Alonso Plasencia
MÉDICO ESPECIALISTA EN NEUMOLOGÍA
Colegiado Nº 38/2860415

Director Gerente

Fdo.:

VºBº Director Médico

hospiten rambla
CLÍNICAS DEL SUR S.L.U.
Rambla de Santa Cruz, 115
38001 - Santa Cruz de Tenerife
T. 922 29 16 00
C.I.F.: B-38031241

Fdo.:Dr.

Gara Fernández Hernández

De: Alicia Fernaud Alberto
Enviado el: viernes, 31 de enero de 2025 9:28
Para: Gara Fernández Hernández
CC: María Elena García-Valdecasas Campelo; Susana Aguilar Castellano; Eider Vargas Roque; Jose Manuel Jorge Pérez
Asunto: Re: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM

Buenos días
Por mi parte de acuerdo
Un saludo

Enviado desde Outlook para Android

Alicia Fernaud Alberto
Directora Gerente Hospiten Rambla

Hospiten

Antes de imprimir este mensaje, asegúrese de que es necesario.

From: Gara Fernández Hernández <gara.fernandez@hospiten.com>
Sent: Friday, January 31, 2025 9:05:55 AM
To: Alicia Fernaud Alberto <alicia.fernaud@hospiten.com>
Cc: María Elena García-Valdecasas Campelo <elena.garcia-valdecasas@hospiten.com>; Susana Aguilar Castellano <saguilar@hospiten.com>; Eider Vargas Roque <eider.vargas@hospiten.com>; Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Subject: RV: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM

Hola buenos dias

Adjunto solicitud por parte del servicio de neumología, para la ampliación del siguiente código SAP para Hospiten Rambla (CONECTOR RECTO 22M-22F) para su consideración y conformidad como responsable económico del Centro

P.D. La Dirección del Centro Hospitalario dispondrá de 15 días para poder dar autorización a esta solicitud, de lo contrario esta Central entenderá que esta solicitud NO es de su afirmación. Posteriormente esta Central Corporativa procederá a la cancelación y/o desestimar dicha solicitud.

Centro Solicitante: HOSPITEN RAMBLA					
				PROPUESTA INCLUSION	
PROVEEDOR				MEDICAL CANARIA	
				COSTE	
SAP	DENOMINACION	RFA	PREST	CAJA	UNIDAD
828358	CONECTOR RECTO 22MM-22F	1963	25	46,25 €	1,85 €
VIGENCIA TARIFA 31/12/2025 PRECIOS PUESTOS EN LA PUERTA DEL HOSPITAL.					

Ruego su conformidad para proceder a la autorización por parte de la Dirección de Compras.

Muchas Gracias.!!

Saludos Cordiales

Gara Fernández Hernández
Dpto. Gestión y Adjudicación de Compras / Purchasing Department

Hospiten

Antes de imprimir este mensaje, asegúrese de que es necesario.

De: Gara Fernández Hernández <gara.fernandez@hospiten.com>
Enviado el: miércoles, 29 de enero de 2025 9:41
Para: Santiago García-Machiñena Díaz <santiago.garcia@hospiten.com>
CC: Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Asunto: RV: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM

Hola buenos dias

Adjunto solicitud para tramitar de rambla , si no hay inconveniente me encargo de esta gestión registro 2025-0163

Saludos

Gara Fernández Hernández
Dpto. Gestión y Adjudicación de Compras / Purchasing Department

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Hospiten

Antes de imprimir este mensaje, asegúrese de que es necesario.

De: Susana Aguilar Castellano <saguilar@hospiten.com>
Enviado el: miércoles, 29 de enero de 2025 9:22

Para: Gara Fernández Hernández <gara.fernandez@hospiten.com>; Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
CC: Eider Vargas Roque <eider.vargas@hospiten.com>; Teresa Martín Pérez <teresa.martin@hospiten.com>; Yayi Acosta <yacosta@hospiten.com>
Asunto: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM

Buenos días
Adjunto solicitud de nuevo material número 14 debidamente firmada por gerencia
*CONECTOR RECTO 22M-22F CON CONEX 6MM
*Solicita: Servicio de neumología Dra. Magdalena Alonso
*Crear para los almacenes NEUM
Muchas gracias, un saludo.

Susana Aguilar Castellano
Aux de compras

MEDICAL CANARIAS S.A.

DELEGACIÓN GRAN CANARIA
C/ Olof Palme nº 31 bajo
35010 Las Palmas de G.C.
Tlfn. 928 22 52 05 - Fax. 928 22 95 23
Email: medical-lp@medicalcanarias.com

DELEGACIÓN TENERIFE
C/ Esperanto nº 4, Bajo, Edificio Daniel II
38280 Tegueste
Tlfn. 922 54 48 53 - Fax. 922 54 49 53
Email: medical-tf@medicalcanarias.com

PRESUPUESTO			
Serie	Número	Fecha	Cliente
TF	25020026	22/01/2025	0857

CLINICAS DEL SUR S.L.U.
AV/MARÍTIMA,3
38003 SANTA CRUZ DE TENERIFE
STA CRUZ DE TENERIFE-ESPAÑA
CIF: B38031241

DATOS COMERCIAL
Este presupuesto le ha sido enviado por Damián Pérez García
Email: dp@medicalcanarias.com Teléfono: 686949702
A la atención de:

Referencia	Descripción	Código Z	Unidades	Precio		Importe
1963	CONECTOR RECTO 22M - 22F CON CONEX. 6 MM C/25		25,00	1,8500		46,25

EAN udad. 5030267057375
EAN caja: 05030267005499

Importe neto				Base I.G.I.C.	%IGIC	Total I.G.I.C.
46,25				46,25	0,00	

VALIDEZ DE LA OFERTA: HASTA EL 31 DE DICIEMBRE DE 2025

* Portes e impuestos incluidos

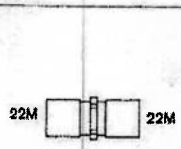
OBSERVACIONES:

TOTAL	46,25

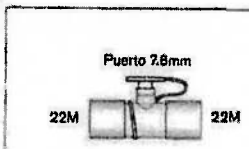
Exento de IGIC - Comerciante Minorista

INSCRITA EN EL REGISTRO MERCANTIL DE LAS PALMAS, FOLIO 210, TOMO 602, Nº 379, SECCIÓN 3ª, HOJA 6676, INSCRIPCIÓN 1ª, CIF A-35139252

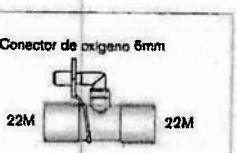
Conectores rectos de 22mm y boquillas



Referencia	1960000 (S*)
Uds./caja	40 (15*)



Referencia	1966000
Uds./caja	25



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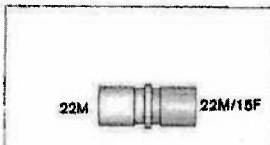
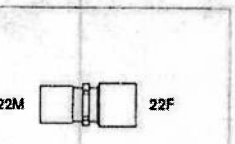
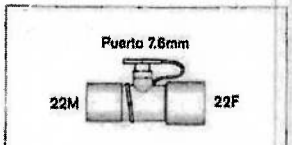
Uds./caja	25



Referencia	1969000 (S*)
Uds./caja	40 (15*)



Referencia	1961000 (S*)
Uds./caja	40 (15*)



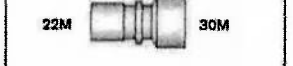
Referencia	1964000 (S*)
Uds./caja	25 (15*)

Referencia	1963000
Uds./caja	25

Referencia	1977000 (S*)
Uds./caja	35 (15*)

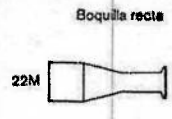
Referencia	1967000 (S*)
Uds./caja	35 (15*)

Referencia	1975000
Uds./caja	50



Referencia	1970000
Uds./caja	35

Referencia	1971000
Uds./caja	25



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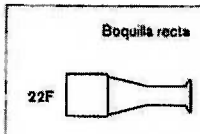
Uds./caja	40

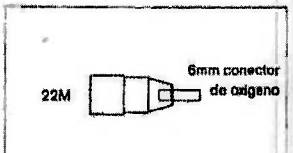


Referencia	1931000
Uds./caja	35

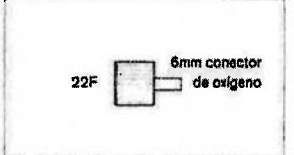
Referencia	1937000
Uds./caja	20

Referencia	1938000
Uds./caja	15

Referencia	1510000
Uds./caja	75



Referencia	1968000
Uds./caja	50



Referencia	1568000
Uds./caja	40

Referencia	1978000
Uds./caja	45


INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
CONNECTOR 22M
- 22F + 6MM STEM
Distributed in the USA by: Intersurgical
Incorporated, 6757 Kinne Street East
Syracuse, NY 13057, T: 800-[illegible]-8633,
support@intersurgicalinc.com
REF 1963000
LOT 31650843
2021-01
LATEX
PHTHALATE-FREE
CE
0120
Rx ONLY 1963000-3-A
MADE BY INTERSURGICAL IN LITHUANIA
5 030267 057375

COMUNICACIÓN DE COMERCIALIZACIÓN Y /O PUESTA EN SERVICIO DE PRODUCTOS SANITARIOS

(Art. 22 del Real Decreto 1591/2009, de 16 de Octubre, por el que se regulan los productos sanitarios)

Con fecha 06 de marzo de 2023 ha tenido entrada en el registro electrónico de la Agencia Española de Medicamentos y Productos Sanitarios, la comunicación de comercialización y/o puesta en servicio del producto:

DENOMINACIÓN
Conectores circuitos respiratorios

COMUNICADO POR

INTERSURGICAL ESPAÑA SLU
ESPAÑA
28935 MOSTOLES
C/ Plasencia 39, Pol. Ind. Las Nieves

FABRICANTE

INTERSURGICAL LTD
REINO UNIDO
RG412RZ Wokingham
Crane House, Molly Millars Lane

REPRESENTANTE EUROPEO AUTORIZADO

UAB INTERSURGICAL
LITUANIA
18170 - Pabrad¿ Pabrad¿
Arnioni¿ g. 60

a la que le ha correspondido el número de identificación en el registro:

PS/2023/02032(D)

El titular de la comunicación está obligado a mantenerla actualizada con las modificaciones que puedan surgir según se establece en el citado Real Decreto.
Este documento debe completarse con el Resumen de comunicación que se puede descargar de la aplicación CCPS en cada momento.

Nota.- Este justificante de comunicación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente. Únicamente avala el cumplimiento del procedimiento de comunicaciones de comercialización y/o puesta en servicio de productos sanitarios.

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: 91 822 54 99
Fax: 91 822 52 89

EC Certificate Full Quality Assurance System: Certificate GB19/964232

The management system of

Intersurgical Ltd.

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 May 2021 until 26 November 2023
and remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 11 January 1995

Certification is based on reports numbered GB/PC 04303

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Sterile and Non-Sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy:
Sterile and Non-Sterile Anaesthetic Breathing Systems
Aerosol and Oxygen Face Masks
Anaesthetic Face Masks
Sterile Endotracheal Tube Introducer and Sterile Airway Stylets
Sterile and Non-Sterile Breathing Systems
Non-Heated Respiratory Bubble Humidifier
Sterile and Non-Sterile Catheter Mounts
Sterile and Non-Sterile Breathing System Connectors
Sterile and Non-Sterile Respiratory Filters
Breathing System Flexible Tubing
High Concentration Oxygen Face Masks
Sterile and Non-Sterile Heat and Moisture Exchangers
Sterile and Non-Sterile HME Filters
Sterile and Non-Sterile Inspiratory Line Humidification Chambers
Sterile I-gel Supraglottic Airways
Sterile Laryngeal Airways
Gas Sampling/Monitoring Respiratory Tubing
Sterile and Non-Sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads)
Electrically Powered Moisture Condenser, Nasal Cannulae
Nebulising System Delivery Sets
Suction and Irrigation Oral Care Toothbrush
Oxygen Administration Tubing
Repeated Use Breathing Systems
Breathing Systems Reservoir Bags
Manual Pulmonary Resuscitation Systems
Carbon Dioxide Absorbents
Sterile and Non-Sterile Tracheal Suction Systems
Sterile Endotracheal Tubes
Venturi Valves and Venturi Valve Face Mask Kits
Wall Humidifier Nebuliser
Breathing System Water Traps
CPAP Bi-level Nasal Masks and NIV Face Masks
Pressure Limiting Valves
Peep Valves One Way Directional Valves
Infant Nasal CPAP Breathing System
Oxygen Recovery Kits
Endoscopy Molar Bite Block
Carbon Dioxide Cuvette

Class I sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Guedel Airways

Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Additional facilities

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

Unit 3, Molly Millars Bridge, RG41 2WY, UK

Dray House, Molly Millars Lane, RG41 2PX, UK

Brook House, Molly Millars Bridge,, RG41 2WY, UK

Unit 1, Molly Millars Lane, RG41 2QZ, UK

Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 2RL, UK

UAB Intersurgical Arnionių g.60, LT-18170 Pabradė, Lithuania

Arnionių g. 60A, Pabradė, LT-18170, Lithuania

Arnionių g. 45, Pabradė, LT-18170, Lithuania

Duksto kelias 84A, Visaginas, LT-31146, Lithuania

Intersurgical Ltd
Crane House, Molly Millars Lane
Wokingham, Berkshire
RG41 2RZ
UK

04/09/2023

Confirmation Letter Reference: CLNB1639 GBPC04303

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Intersurgical Ltd
Crane House, Molly Millars Lane
Wokingham, Berkshire
RG41 2RZ
UK
SRN number: GB-MF-000004798

Authorised Representative
UAB Intersurgical
Arnionių g. 60
LT-18170 Pabradė,
Lithuania
SRN number: LT-AR-000003907

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile and Non-Sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy: -Sterile and Non-Sterile Anaesthetic Breathing Systems	IIa	N/A	GB19/964232; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05030267ABSL6 -Aerosol and Oxygen Face Masks 05030267AEROXY65 Anaesthetic Face Masks 05030267AMSKBX Sterile Endotracheal Tube Introducer and Sterile Airway Stylets 05030267BOUGCE Sterile and Non-Sterile Breathing Systems 05030267BS2M Non-Heated Respiratory Bubble Humidifier 05030267BUBHUM6E Sterile and Non-Sterile Catheter Mounts 05030267CATHMT3K Sterile and Non-Sterile Breathing System Connectors 05030267CONNR8V Sterile and Non-Sterile Respiratory Filters 05030267FILTER6S Breathing System Flexible Tubing 05030267FLEXTU8H High Concentration Oxygen Face Masks			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05030267HICON7E Sterile and Non-Sterile Heat and Moisture Exchangers 05030267HMEME Sterile and Non-Sterile HME Filters 05030267HMEFBU Sterile and Non-Sterile Inspiratory Line Humidification Chambers 05030267HUMCHA4 Sterile I-gel Supraglottic Airways 05030267IGELBH Sterile Laryngeal Airways 05030267LMAMS Gas Sampling / Monitoring Respiratory Tubing 05030267MONTUBCM Sterile and Non-Sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads) 05030267HW3F Electrically Powered Moisture Condenser, 05030267INTCOOLDZ Nasal Cannulae 05030267NACAN6E			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Nebulising System Delivery Sets 05030267NEBME Suction and Irrigation Oral Care Toothbrush 05030267ORANGE9K Oxygen Administration Tubing 05030267OXYTUBJX Repeated Use Breathing Systems 05030267REPSYSCX Breathing Systems Reservoir Bags 05030267RESBAG7X Manual Pulmonary Resuscitation Systems 05030267RESUSDC Carbon Dioxide Absorbents 05030267SODAE6 Sterile and Non-Sterile Tracheal Suction Systems 05030267SUCSYSFZ Sterile Endotracheal Tubes 05030267TRACTUBFN Venturi Valves and Venturi Valve Face Mask Kits 05030267VNTURIHK Wall Humidifier Nebuliser 05030267WALNEB8Z			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Breathing System Water Traps 05030267WT4N CPAP Bi-level Nasal Masks and NIV Face Masks 05030267CPNVMASKN6 Pressure Limiting Valves 05030267PLVALVEGW Peep Valves 05030267PVALVECF One Way Directional Valves 05030267OWVALVELU Infant Nasal CPAP Breathing System 05030267NFLOWAS Oxygen Recovery Kits 05030267OXYRECH7 Endoscopy Molar Bite Block 05030267BITEBLOCKR9 Carbon Dioxide Cuvette 05030267STREAMMONBW			
Sterile Guedel Airways 05030267GUEDEL6W	Is	N/A	GB19/964232; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/04	Version 1	Initial issue

INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, Crane House, Molly Millars Lane,
Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 9656 300 F: +44 (0)118 9656 356
info@intersurgical.com www.intersurgical.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Intersurgical Ltd
Manufacturer address and contact details	Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ United Kingdom Tel: +44 (0) 118 9656 300 Fax: +44 (0) 118 9656 356
Single Registration Number (SRN) (if available)	GB-MF-000004798

Authorised Representative name (if applicable)	UAB Intersurgical
Authorised Representative address and contact details	Arnionių 60, Pabradė, LT-18170, Lithuania Tel: +370 387 66611 Fax: +370 387 66622
Single Registration Number (SRN) (if available)	LT-AR-000003907

Notified body name (if applicable)	SGS Belgium NV □ See attached schedule
Notified body number (if applicable)	1639 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	GB19/964232 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 November 2023 □ See attached schedule
End date of extended validity/transition period	31 December 2028 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

✓ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.

The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	Intersurgical Ltd.
Location & Date:	Wokingham, 5 October 2023
Signature, Print Name, Title:	Ivan Seniut Group Quality and Regulatory Affairs Director Duly authorised for and on behalf of Intersurgical Ltd
Contact Details (at least email):	00 370 38766 609 is@intersurgical.co.uk

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile and Non-Sterile Anaesthetic Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Aerosol and Oxygen Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Anaesthetic Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Endotracheal Tube Introducer and Sterile Airway Stylets	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Non-Heated Respiratory Bubble Humidifier	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile	GB19/964232	26 November 2023	SGS Belgium	SGS Belgium NV,	31 December	Not applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Catheter Mounts			NV, Notified Body 1639	Notified Body 1639	2028	
Sterile and Non-Sterile Breathing System Connectors	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Respiratory Filters	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing System Flexible Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
High Concentration Oxygen Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Heat and Moisture Exchangers	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile HME Filters	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile and Non-Sterile Inspiratory Line Humidification Chambers	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile I-gel Supraglottic Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Laryngeal Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Gas Sampling/Monitoring Respiratory Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Sterile and Non-Sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads)	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Electrically Powered Moisture Condenser	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Nasal Cannulae	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Nebulising System Delivery Sets	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Suctions and Irrigation Oral Care Toothbrush	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Oxygen Administration Tubing	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Repeated Use Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing Systems Reservoir Bags	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Manual Pulmonary Resuscitation Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Carbon Dioxide Absorbents	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Sterile and Non-Sterile Trachseal Suction Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Endotracheal Tubes	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Venturi Valves and Venturi Valve Face Mask Kits	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Wall Humidifier Nebuliser	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Breathing System Water Traps	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
CPAP Bi-level Nasal Masks and NIV Face Masks	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Pressure Limiting Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Peep Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
One Way Directional Valves	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Infant Nasal CPAP Breathing Systems	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Oxygen Recovery Kits	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Endoscopy Molar Bite Block	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Carbon Dioxide Cuvette	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable
Sterile Guedel Airways	GB19/964232	26 November 2023	SGS Belgium NV, Notified Body 1639	SGS Belgium NV, Notified Body 1639	31 December 2028	Not applicable

Gara Fernández Hernández

De: Damián Pérez <dp@medicalcanarias.com>
Enviado el: viernes, 31 de enero de 2025 8:23
Para: Gara Fernández Hernández
CC: 'Medical Canarias'
Asunto: RE: OFERTA 25020026
Datos adjuntos: Justificante_de_Comunicacion -conectores circuitos respiratorios.pdf; Carta fabricante extensión validez certificado CE Intersurgical.pdf; Carta NB extensión certificado y acuerdo MDR Intersurgical.pdf; Certificado CE Sistema Garantía Calidad (marcado CE) Intersurgical.pdf

Buenos días Gara,
Adjunto la documentación enviada por el fabricante de los conectores marca Intersurgical .

Un saludo,

Damián Pérez
Movil: 686 949702
E-mail: dp@medicalcanarias.com
MEDICAL CANARIAS S.A.
TELF: +34 922 544853
FAX : +34 922 544953

De: Gara Fernández Hernández
Enviado el: jueves, 30 de enero de 2025 15:35
Para: medical-tf@medicalcanarias.com; dp@medicalcanarias.com
Asunto: RE: OFERTA 25020026

Hola buenas tardes

Solo es a titulo recordatorio

Saludos

Gara Fernández Hernández
Dpto. Gestión y Adjudicación de Compras / Purchasing Department

Avenida Marítima, 3
38003 Santa Cruz de Tenerife
Islas Canarias Spain
T (+34) 922 629 470

hospiten.com

Hospiten

Antes de imprimir este mensaje, asegúrese de que es necesario.

De: Gara Fernández Hernández <gara.fernandez@hospiten.com>
Enviado el: miércoles, 29 de enero de 2025 9:56
Para: medical-tf@medicalcanarias.com; dp@medicalcanarias.com
Asunto: OFERTA 25020026

Hola buenos dias

Necesito de vuestra ayuda nos ha llegado de parte de rambla el siguiente presupuesto numero 25020026 de un conector recto , me faltaría la siguiente documentación por favor para poder dar de alta el material en nuestro sistema .

1- Certificado Registro Sanitario de dicho material.

2- Certificados CE, de calidad, medido Ambiente y/o seguridad, dependiendo del tipo de producto o material.

saludos

Gara Fernández Hernández
Dpto. Gestión y Adjudicación de Compras / Purchasing Department

Avenida Marítima, 3
38003 Santa Cruz de Tenerife
Islas Canarias Spain
T (+34) 922 629 470

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Gara Fernández Hernández

De: Gara Fernández Hernández
Enviado el: viernes, 31 de enero de 2025 13:21
Para: Lorenzo Galán
CC: Susana Aguilar Castellano; Eider Vargas Roque; Jose Manuel Jorge Pérez
Asunto: RV: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM
Datos adjuntos: AMPLIACION 828358 CONECTOR RECTO 22MM.xlsx

Buenas tardes

En el día de hoy se ha dado autorización para la inclusión y ampliación para Rambla del siguiente material (828358 conector recto 22mm-22f)

ALMACEN: NEUM

	Centro Solicitante: HOSPITEN RAMBLA				
				PROPUESTA INCLUSION	
	PROVEEDOR			**MEDICAL CANARIA**	
				COSTE	
SAP	**DENOMINACION**	**RFA**	**PREST**	**CAJA**	**UNIDAD**
828358	**CONECTOR RECTO 22MM-22F**	**1963**	**25**	**46,25 €**	**1,85 €**
	VIGENCIA TARIFA 31/12/2025				
	PRECIOS PUESTOS EN LA PUERTA DEL HOSPITAL.				

El Centro Hospitalario se responsabilizará que dicho material sea facturado al paciente y/o Entidad Aseguradora Pública o Privada, con especial atención a pacientes de Entidades Aseguradoras las cuales requieran consentimiento y autorización previa antes de su uso o aplicación.

Si el paciente es asegurado de Entidades quienes tienen acuerdos con proveedores, previamente la Dirección o Administración del Hospital deberá verificar las marcas y/o proveedores homologados por la Entidad.
En caso de que el paciente pertenezca a Entidades Aseguradoras Públicas o Privadas con quienes tengamos "Tarifa de Prestación Cerrada", antes de dar conformidad la Dirección del Hospital deberá analizar el coste del material junto con la tarifa de prestación.

Saludos

De: Alicia Fernaud Alberto <alicia.fernaud@hospiten.com>
Enviado el: viernes, 31 de enero de 2025 9:28
Para: Gara Fernández Hernández <gara.fernandez@hospiten.com>
CC: María Elena García-Valdecasas Campelo <elena.garcia-valdecasas@hospiten.com>; Susana Aguilar Castellano <saguilar@hospiten.com>; Eider Vargas Roque <eider.vargas@hospiten.com>; Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Asunto: Re: SOLICITUD NUEVO MATERIAL NÚMERO14 CONECTOR RECTO 22M-22F CON CONEX 6MM