2025 - 0276

Centro Solicitante: HOSPITEN ESTEPONA

	PROVEEDOR			PROPUESTA INCLUSION MEDCOMTECH
SAP	DENOMINACION	RFA	PREST	COSTE UNIDAD
CREAR	AGUJA DE SUTURA LASSO LOOP	810503400	1	180,00 €

TE 2213

VIGENCIA TARIFA 31/12/2025
PRECIOS SIN EL 21% DE IVA

	A rellenar por el centro,Marcar con una X si el Material Sanitario es NO facturable.			
	ADESLAS	DKV	SANITAS	
Amb.				
Hosp.				

queirefno

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:MT(Material de traumatologia).
CLASE: MT01 (Consumibles).
CARACTERISTICAS: MT0106(AGUJAS).

Informe y/o Gestión realizada por:
Gara Fernandez Hernandez

Fdo.:

7/03/2025

MODELO 1. ADMISIÓN DE NUEVOS MATERIALES

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

1. **Nombre y referencia material:** Suture Lasso Wire Loop (Ref. 810503400)
2. **Nombre comercial:** Aguja de Sutura Lasso Loop
3. **Laboratorio:** Medcomtech (12204)
4. **Presentación:** 1 UD.
5. **Aplicación:**

   Los pasadores de sutura están diseñados para pasar tanto la sutura a través del tejido dle labrum en un procedimiento artroscópico de hombro, como para un menisco en la rodilla

6. **Descripción del producto:**

   Los pasadores de sutura son dispositivos manuales sin motor destinados a pasar la sutura a través del tejido

7. **Reséñese la acción diagnóstica/terapéutica principal y el uso terapéutico del material que justifique su inclusión:**

   En la aguja de sutura la longitud total del lazo de sutur es de 560 mm, la longitud de la aguja bucle es de 90 mm.

8. **Materiales de uso actual en Hospiten código SAP:**

   No existe

9. **Razones clínicas por las cuales este material es superior a los citados anteriormente:**

10. **¿Qué materiales considera usted podrían retirarse de la Guía reseñados anteriormente?**

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

Dr. Manuel Vidés Fernández
Nº Colegiado: 2909092

Fdo.: Dr.

Director Gerente

Fdo.: D. GERARDO BRAVO

V°B° Director Médico

Dr. José Carlos Salas Serantes
Nº Colegiado: 29/38/06698
Director Médico

Fdo.:Dr.

Gara Fernández Hernández

De: Gerardo Bravo Chaparro
Enviado el: jueves, 6 de marzo de 2025 17:01
Para: Gara Fernández Hernández
CC: Jose Carlos Salas Serantes; Compras Estepona; Jose Manuel Jorge Pérez
Asunto: RE: Solicitud alta material - Ref. 810503400 (Medcomtech)

Buenas tardes,

Se autoriza

Un saludo.

Gerardo Bravo Chaparro
Director Gerente de Hospiten Estepona

Hospiten

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

De: Gara Fernández Hernández <gara.fernandez@hospiten.com>
Enviado el: jueves, 6 de marzo de 2025 17:58
Para: Gerardo Bravo Chaparro <gerardo.bravo@hospiten.com>
CC: Jose Carlos Salas Serantes <josecarlos.salas@externo.hospiten.com>; Compras Estepona <comprasestepona@hospiten.com>; Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Asunto: RV: Solicitud alta material - Ref. 810503400 (Medcomtech)

Buenos días,

Adjunto solicitud por parte del servicio quirófano, junto con coste económicos con de lo solicitado (AGUJA DE SUTURA LASSO LOOP) 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 ESTEPONA			
				PROPUESTA INCLUSI
	PROVEEDOR			**MEDCOMTECH**
				COSTE
SAP	**DENOMINACION**	**RFA**	**PREST**	**UNIDAD**
CREAR	**AGUJA DE SUTURA LASSO LOOP**	**810503400**	**1**	**180,**
	VIGENCIA TARIFA 31/12/2025			
	PRECIOS SIN EL 21% DE IVA			

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

De: Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Enviado el: miércoles, 19 de febrero de 2025 14:39
Para: Santiago García-Machiñena Díaz <santiago.garcia@hospiten.com>
CC: Gara Fernández Hernández <gara.fernandez@hospiten.com>
Asunto: RV: Solicitud alta material - Ref. 810503400 (Medcomtech)

Buenos días,
Santi, por favor, para asignar la persona que consideres oportuno y lleve a cabo esta SOLICITUD.

Registro Número 2025/0276.

Gracias.

Saludos Cordiales

Responsable Fungibles y Prótesis.

Jose Manuel Jorge Pérez
Dpto. Gestión y Adjudicación de Compras / Purchasing Department

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Hospiten

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

De: Compras Estepona <comprasestepona@hospiten.com>
Enviado: miércoles, 19 de febrero de 2025 14:32
Para: Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Cc: Gerardo Bravo Chaparro <gerardo.bravo@hospiten.com>
Asunto: Solicitud alta material - Ref. 810503400 (Medcomtech)

Buenas tardes José Manuel:

Necesitamos dar de alta la siguiente referencia de material del proveedor Medcomtech (12204) correspondiente al vale 13427 (línea 3-4) y 13440 (línea 3) del episodio 21786123:

- **Ref. 810503400** Aguja sutura Lasso Loop

Adjunto remito solicitud de nuevos materiales, vales 13727-13440, oferta económica y Ficha Técnica correspondiente. El paciente tiene garantía Mapfre. Para cualquier cuestión quedamos a tu disposición.

Saludos!
David Valadez Guillén

Compras Estepona
Compras Hospiten Estepona

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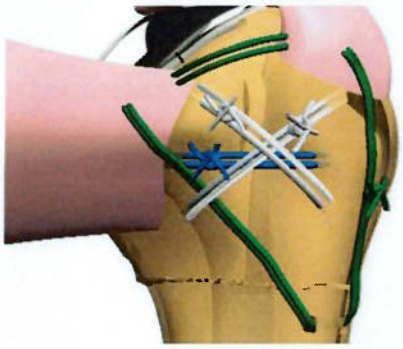
medcomtech
Innovation.Technology.Service

LISTAS DE PRECIOS

Precios vigentes hasta nuevo aviso

REFERENCIA	DESCRIPCIÓN	Precio S/IGIC	Rappel 2025
312-3208	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø32/08 Ti/HA	1.485,00	10%
312-3610	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø36/10 Ti/HA	1.485,00	10%
312-4012	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø40/12 Ti/HA	1.485,00	10%
317-4014	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø40/14 Ti/HA	1.485,00	10%
312-3210	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø32/10 Ti/HA	1.485,00	10%
312-3212	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø32/12 Ti/HA	1.485,00	10%
312-3612	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø36/12 Ti/HA	1.485,00	10%
312-3614	VÁSTAGO INVERTIDO HUMELOCK SIN CEMENTAR Ø36/14 Ti/HA	1.485,00	10%
770-135-000-002	Placa H proximal INTEOS 3,5 as av T 8/2 izq.	1.080,00	15%
770-135-000-003	Placa H proximal INTEOS 3,5 as av T 8/3 izq.	1.080,00	15%
770-135-000-004	Placa H proximal INTEOS 3,5 as av T 8/4 izq.	1.080,00	15%
770-135-000-006	Placa H proximal INTEOS 3,5 as av T 8/6 izq.	1.080,00	15%
770-135-000-006-S	Placa H proximal INTEOS 3,5 as av T 8/6 izq. Esteril	1.200,00	15%
770-135-000-009-S	Placa H proximal INTEOS 3,5 as av T 8/9 izq. Esteril	1.320,00	15%
770-135-000-012-S	Placa H proximal INTEOS 3,5 as av T 8/12 izq. Estéril	1.560,00	15%
770-135-000-015-S	Placa H proximal INTEOS 3,5 as av T 8/15 izq. Estéril	1.800,00	15%
770-135-000-018-S	Placa H proximal INTEOS 3,5 as av T 8/18 izq. Estéril	1.920,00	15%
292-1001	tloop USP 5 (7.0 Metric) Polyester Blanco L.=100mm. Sutura Loop de alta resist	168,00	10%
292-1003	tloop USP 5 (7.0 Metric) Polyester Verde L.=100mm. Sutura Loop de alta resist	168,00	10%
777-112-060-003	Placa palmar INTEOS M4 2.5 wsl T 9/3 izq. estrecho	684,00	15%
777-112-060-005	Placa palmar INTEOS M4 2.5 wsl T 9/5 izq. estrecho	684,00	15%
777-112-061-003	Placa palmar INTEOS M4 2.5 wsl T 9/3 dcha. estrecho	684,00	15%
777-112-061-005	Placa palmar INTEOS M4 2.5 wsl T 9/5 dcha. estrecho	684,00	15%
777-112-000-003	Placa palmar INTEOS M4 2.5 wsl T 9/3 izq.	780,00	15%
777-112-000-005	Placa palmar INTEOS M4 2.5 wsl T 9/5 izq.	780,00	15%
777-112-001-003	Placa palmar INTEOS M4 2.5 wsl T 9/3 dcha.	780,00	15%
810503400	Aguja de Sutura Lasso Loop	180,00	-
810501700	EasyPass Aguja, MultiFire	180,00	-
810500100	EasyPass Pasador de sutura, Tipo rana 45° Derecho	490,00	-
810500200	EasyPass Pasador de sutura, Tipo rana 45° Izquierdo	490,00	-
810500700	EasyPass Pasador de sutura, Tipo rana Medialuna	490,00	-
810503500	EasyPass Pasador de sutura, tipo Rana 70° Recto	490,00	-
810805200	Pin Guia 1,2mm	30,00	-

FICHA DE PRODUCTO



1. Nombre del producto

Sutura quirúrgica SMARTLOOP

2. Fabricante

DEMETECH CORPORATION

14175 NW 60th Ave, Miami Lakes, FL 33014 – USA

Tel: (305) 824 1048 – Fax: (305) 437-7607

3. Indicación de uso

SMARTLOOP son suturas especialmente diseñadas para suturar el complejo formado por la prótesis de fracturas con las tuberosidades y la diáfisis.

Características:

AGUJA:

- tamaño: 1.8mm y longitud 40mm;
- curvatura: 135° (3/8 círculo);
- tipo de punta: triangular, punta de corte cónico.

SUTURA:

- calibre del hilo: diámetro de 1,2 mm (USP 5);
- longitud del bucle: 1000mm;
- resistencia: resistencia 32kg.

4. Método de esterilización

SMARTLOOP se entrega estéril, esterilizado por rayos gamma.

5. Condiciones de almacenamiento

Conservar por debajo de 25ºC y mantener lejos de fuentes directas de calor y humedad.

6. Ausencia de látex

Si

7. Ausencia de ftalatos

Si

8. Interferencia con Imagen por Resonancia Magnética (IRM)

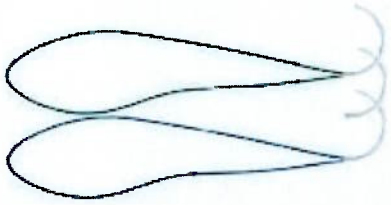
No

9. Radiolucente

No

COMPONENTES

a) Sutura
- Composición: Tetraftalato de polietileno (PET)
- Regulación: clase IIb



b) Aguja
- Composición: Acero inoxidable
- Regulación: clase IIb

REFERENCIAS Y MODELOS

292-1001	SMARTLOOP WHITE USP 5
292-1003	SMARTLOOP GREEN USP 5

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 095193 0006 Rev. 01

Manufacturer:

Hangzhou Rejoin Mastin Medical Device Co.,Ltd.
Floors 1st and 2nd, 101B
No 22 Xinyan Road
Yuhang Economic Development Zone
311100 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hangzhou Rejoin Mastin Medical Device Co.,Ltd.
Floors 1st and 2nd, 101B, No 22 Xinyan Road, Yuhang Economic Development Zone, 311100 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Cannulas,
Knot Pusher/Suture Cutter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19104705

Valid from: 2020-02-03
Valid until: 2024-03-06

Date, 2020-02-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 095193 0014 Rev. 00

Manufacturer:

Hangzhou Rejoin Mastin Medical Device Co.,Ltd.
Floors 1st and 2nd,101B
No. 22, Xinyan Road
Economic and Technological Development Zone
Linping District
311100 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2 095193 0006 Rev. 01

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 095193 0014 Rev. 00

Report No.: SH22104701

Valid until: 2024-03-06

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-04-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 095193 0014 Rev. 00

Product Category(ies): **Cannulas,**
Knot Pusher/Suture Cutter

Description of Change:

Change of address from "Floors 1st and 2nd,101B, No. 22, Xinyan Road, Economic and Technological Development Zone, Yuhang District, 311100 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA" to "Floors 1st and 2nd,101B, No. 22, Xinyan Road, Economic and Technological Development Zone, Linping District, 311100 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA"

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TÜV

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Economic and Technological Development Zone
Floors 1st and 2nd,101B
No. 22, Xinyan Road
Linping District
311100 HANGZHOU, ZHEJIANG
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	713273847 | 713316269	+86 21 61424365	NA	2024-03-15	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 095193 0015 Rev. 02

Reference: 713273847 | 713316269

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000006572

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 095193 0015 Rev. 02

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-15

TÜV SÜD Product Service GmbH
Medical and Health Services

Zhu Bin
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Claus Matthias Mumme
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 1 **Ti Suture Anchors** **Basic UDI -DI:** **697387766P2015002004P** **697387766P2015002014P**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123 Certificate # G1 095193 0009 Rev.00 (GCQ 095193 0013 Rev. 00); NB# 0123
Device 2 **PEEK Suture Anchors** **Basic UDI -DI:** **697387766P20150050056** **697387766P20150050156**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123 Certificate # G1 095193 0009 Rev.00 (GCQ 095193 0013 Rev. 00); NB# 0123
Device 3 **All-suture Anchors** **Basic UDI -DI:** **69418325P2015006009B** **697387766P2015006005B**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123
Device 4 **Suture Passers** **Basic UDI -DI:** **697387766RD032100400WE**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class III implantable custom-made-device		
Device 5 **Meniscal Repair System** **Basic UDI -DI:** **697387766P20140010045**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0009 Rev.00 (GCQ 095193 0013 Rev. 00); NB# 0123
Device 6 **Cannulas** Basic UDI-DI: **697387766P20160030059**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2 095193 0006 Rev.01 (GCQ 095193 0014 Rev. 00); NB# 0123
Device 7 **Knot Pusher & Suture Cutter** Basic UDI-DI: **697387766P2015007005G**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2 095193 0006 Rev.01 (GCQ 095193 0014 Rev. 00); NB# 0123
Device 8 **Non-absorbable Surgical Suture** Basic UDI-DI: **697387766P2016001004X** **69418325P2016001008X** **69418325P2016001018Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 9 **Drills** Basic UDI-DI: **697387766P2018010005T** **69418325P2018010019V**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123
Device 10 **Graft Prepare System** Basic UDI-DI: **697387766P2018006006J**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G1 095193 0007 Rev.02 (GCQ 095193 0012 Rev. 00); NB# 0123
Device 11 **PEEK Suture Anchors** Basic UDI-DI: **6941832520150050O2EG**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0009 Rev.00 (GCQ 095193 0013 Rev. 00); NB# 0123
Device 12 **Blades** Basic UDI-DI: **69418325P2014002008A** **697387766P2014002004A** **69418325P2014002048J**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #G2 095193 0010 Rev.00 (GCQ 095193 0011 Rev. 00); NB# 0123
Device 13 **Burrs**	☐ Class III	☒ N/A	☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Basic UDI-DI: **69418325P2014002028E** **697387766P2014003004F**	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		Certificate # G2 095193 0010 Rev.00 (GCQ 095193 0011 Rev. 00); NB# 0123
Device 14 **PEEK Interference Screw** **Basic UDI-DI:** **697387766P2015001004J** **69418325P2015001008J** **69418325P2015001018L**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 095193 0009 Rev.00 (GCQ 095193 0013 Rev. 00); NB# 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-01-11	713273847 | 713316269	Initial issue
2024-03-14	713273847 | 713316269	Added device 6-14 in table 1 named Cannulas, Knot Pusher & Suture Cutter, Non-absorbable Surgical Suture, Drills, Graft Prepare System, PEEK Interference Screw, Blades, Burrs, PEEK suture anchor.
2024-03-15	713273847 | 713316269	Certificate number of devices #12 & #13 corrected

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	Hangzhou Rejoin Mastin Medical Device Co., Ltd.
Manufacturer address and contact details	Floors 1st and 2nd, 101B, No. 22 Xinyan Rd., Economic and Technological Development Zone, Linping District, 311100, Hangzhou, Zhejiang, People's Republic of China
Single Registration Number (SRN) (if available)	CN-MF-000006572

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH(Europe)
Authorised Representative address and contact details	Eiffestrasse 80, 20537, Hamburg, Germany
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	TÜV SÜD Product Service GmbH
Notified body number (if applicable)	CE 0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	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.

End date of extended validity/transition period	See attached schedule

Notified body name (if applicable)	DEKRA Certification B.V.
Notified body number (if applicable)	CE 0344
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	See attached schedule

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)

[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

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:

☑ 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.

➢ **Unclassified 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: Hangzhou Rejoin Mastin Medical Device Co., Ltd.

Location & Date: Hangzhou, 2024-07-19

Signature, Print Name, Title: Zhang Zhang, RA Director

Contact Details (at least email): zhang.zhang@rejoin.com

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)
Cannulas	G2 095193 0006 Rev.01	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Knot Pusher/Suture Cutter	G2 095193 0006 Rev.01	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Ti Suture Anchors	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
PEEK Suture Anchors	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
All Suture Anchors	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Non-absorbable Surgical Suture	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Suture Passer	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA

[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)

Drills	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Graft Prepare System	G1 095193 0007 Rev.02	2024-03-06	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Meniscal Repair System	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Small PEEK Suture Anchors	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Suture Buttons	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with Dekra CE 0344	2028-12-31	NA
PEEK Interference Screw	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Mini Ti Suture Anchors	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Loop Buttons	G1 095193 0009 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with Dekra CE 0344	2028-12-31	NA
Burrs	G2 095193 0010 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Blades	G2 095193 0010 Rev.00	2024-05-26	TÜV SÜD CE 0123	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA
Surgical instrument	NA (These devices are classified Ir which conformity assessment procedure pursuant to MDD did not require the involvement of a notified body)	2024-05-26	NA	MDR contract was signed with TÜV SÜD CE 0123	2028-12-31	NA

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DECLARACIÓN EN RELACIÓN A LOS ACUERDOS DE FACTURACIÓN DIRECTA CON MUTUAS

El Sr. D. Alejandro Roca de Viñals Delgado, con domicilio en Barcelona, calle Valencia, número 137 y como apoderado de la empresa MEDCOMTECH, S.A, con domicilio fiscal en Alcobendas (Madrid) y a efectos de las notificaciones en Viladecans (Barcelona), calle Antonio Machado, números 78-80 Edificio Australia del Viladecans Business Park, y NIF. número A83015370,

DECLARA BAJO SU RESPONSABILIDAD,

- Que la empresa a la que represento, MEDCOMTECH, S.A, dispone a fecha de hoy de acuerdos comerciales y de facturación directa con las MUTUAS que a continuación les detallamos:

1. ADESLAS
2. SANITAS
3. DKV
4. ASISA
5. DIVINA PASTORA
6. OCCIDENTE
7. MAPHRE
8. AXA
9. FIAT
10. MUTUA FUTBOLISTAS
11. HNA

Y para que así conste, a todos los efectos, firmo la presente declaración responsable en Viladecans, a día 1 de Enero del 2025.

46579841B ALEJANDRO ROCA DE VIÑALS (R: A83015370)

Firmado digitalmente por 46579841B ALEJANDRO ROCA DE VIÑALS (R: A83015370)
Fecha: 2024.04.02 12:33:33 +02'00'

Fdo. Alejandro Roca de Viñals Delgado
APODERADO

Gara Fernández Hernández

De: Gara Fernández Hernández
Enviado el: miércoles, 19 de febrero de 2025 17:34
Para: Ivette Roig Zamora; Jesús Omar García Sánchez; Laura Cepeda Sánchez
CC: Jose Manuel Jorge Pérez
Asunto: RE: SOLICITUD PPTO GRUPO HOSPITEN MUY URGENTE

Hola buenas tardes

Ruego que por favor, nos haga llegar en la mayor brevedad posible, la siguiente información que a continuación pasó a detallar para el Grupo Hospiten.

1- Ficha Técnica o Catalogo.

2- Certificado Registro Sanitario de dicho material.

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

4- Vigencia Tarifa como mínimo 31 de Diciembre 2025

5- Rappel que Grupo Hospiten va tener cuando MEDCOMTECH vaya a facturar directamente a Hospiten.

6- Detalle de las Entidades Aseguradoras Privadas con las que MEDCOMTECH tenga acuerdos a efectos de facturación directa.

7- Los precios a presentar en este Departamento Central, deberán ser precios puestos en la puerta del hospital. Se entiende como precios puestos en la puerta del hospital, con impuestos, transportes, aduanas, etc.. incluidos.

8- Precio Referencia S.C.S

9- Marca y modelo.

10- Presupuesto del siguiente material que a continuación paso a detallar:

Sutura lasso wire loop referencia 810503400
Gracias.

Saludos Cordiales

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

Gara Fernández Hernández

De: Gara Fernández Hernández
Enviado el: viernes, 7 de marzo de 2025 9:26
Para: Lorenzo Galán
CC: Compras Estepona; Jose Manuel Jorge Pérez
Asunto: RV: Solicitud alta material - Ref. 810503400 (Medcomtech)
Datos adjuntos: SOLICITUD ALTA AGUJA SUTURA LASSO.xlsx

Hola buenos dias

En el día de hoy se ha dado autorización para la creación del siguiente material para Hspiten Estepona en el proveedor medcomtech

ALMACEN: QUIROFANO

	Centro Solicitante: HOSPITEN ESTEPONA			
				PROPUESTA INCLUSI(
	PROVEEDOR			MEDCOMTECH
				COSTE
SAP	DENOMINACION	RFA	PREST	UNIDAD
CREAR	AGUJA DE SUTURA LASSO LOOP	810503400	1	180,(
	VIGENCIA TARIFA 31/12/2025			
	PRECIOS SIN EL 21% DE IVA			

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: Gerardo Bravo Chaparro <gerardo.bravo@hospiten.com>
Enviado el: jueves, 6 de marzo de 2025 17:01
Para: Gara Fernández Hernández <gara.fernandez@hospiten.com>
CC: Jose Carlos Salas Serantes <josecarlos.salas@externo.hospiten.com>; Compras Estepona <comprasestepona@hospiten.com>; Jose Manuel Jorge Pérez <josemanuel.jorge@hospiten.com>
Asunto: RE: Solicitud alta material - Ref. 810503400 (Medcomtech)

Buenas tardes,

Se autoriza