EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Lacey Manufacturing Company, LLC

1146 Barnum Avenue,Bridgeport, Connecticut, 06610, United States

Manufacturer SRN: US-MF-000037674

Authorised Representative Name

Emergo Europe B.V,

Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands

Scope:

- Electrosurgical instruments
- Single use surgical instruments

Certificate Number:
28620146584

Revision:
04

Initial Certification Date:
19 April 2023

Certificate Decision Date:
17 January 2025

Certificate Issue Date:
17 January 2025

Certificate Expiry Date:
26 June 2027

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**CN00107-009**
Audit Report Reference	**CN00107-009**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620146584	19 April 2023	Initial Certificate
28620146584-01	24 April 2023	Correction of client name
28620146584-02	31 July 2023	Extension of scope
28620146584-03	15 May 2024	Change of name
28620146584-04	17 January 2025	Correction of SRN number

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PRODUCT LIST FOR CERTIFICATE

Issued to: Lacey Manufacturing Company, LLC

Certificate number: 28620146584-04

Certificate valid from: 2024-01-17

Product List Issue Date:
17 January 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Electrosurgical instruments			
Basic UDI-DI: 0853508002TD01U6			
1560-02 - BAYONET ELECTROSURGICAL PENCIL	Class IIb	Intended for resection, ablation, excision, hemostasis of blood vessels, and coagulation of soft tissue during surgical procedures requiring deep wounds	2023-04-19
9569575 - BAYONET ELECTROSURGICAL PENCIL	Class IIb	Intended for resection, ablation, excision, hemostasis of blood vessels, and coagulation of soft tissue during surgical procedures requiring deep wounds	2023-04-19
Basic UDI-DI: 0853508002TD02U8			
1590-00 - BAYONET BIPOLAR FORCEPS, ANGLED TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
1590-01 - BAYONET BIPOLAR FORCEPS, STRAIGHT TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
1590-02 - BAYONET BIPOLAR FORCEPS, ANGLED TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
1590-03 - BAYONET BIPOLAR FORCEPS, STRAIGHT TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
1590-07 - BAYONET BIPOLAR FORCEPS, STRAIGHT TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
1590-10 - BAYONET BIPOLAR FORCEPS, STRAIGHT TIP, 190mm	Class IIb	Intended to facilitate tissue grasping and control the bleeding of small vessels by bipolar coagulation	2023-04-19
Single use surgical instruments			
Basic UDI-DI: 0853508002TD03UA			
1563-00 - BAYONET SURGICAL KNIFE, 188mm	Class IIa		2023-07-31
1563-01 - BAYONET SURGICAL KNIFE, 188mm	Class IIa		2023-07-31
1563-02 - BAYONET SURGICAL KNIFE, 188mm	Class IIa		2023-07-31
1564-00 - BAYONET SURGICAL KNIFE, 134mm	Class IIa		2023-07-31
1571-00 - SHEATHED SURGICAL KNIFE, 160mm	Class IIa		2023-07-31
1587-00 - BAYONET ANNULOTOMY KNIFE, 193mm	Class IIa		2023-07-31

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
1587-01 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-02 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-03 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-04 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-05 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-06 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-07 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-08 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1587-09 - SHEATHED BAYONET SURGICAL KNIFE, 193mm	Class IIa		2023-07-31
1600-01 - BAYONET SURGICAL KNIFE, 170mm	Class IIa		2023-07-31
1600-02 - BAYONET SURGICAL KNIFE, 170mm	Class IIa		2023-07-31
Basic UDI-DI: 0853508002TD04UC			
PK1001 - PAK NEEDLE- BEVEL/BEVEL	Class IIa		2023-07-31
PK1002 - PAK NEEDLE- TROCAR/TROCAR	Class IIa		2023-07-31
PK1003 - PAK NEEDLE- BEVEL/TROCAR	Class IIa		2023-07-31
PK1004 - XPAK NEEDLE- BEVEL	Class IIa		2023-07-31
PK1005 - XPAK NEEDLE- TROCAR	Class IIa		2023-07-31
Basic UDI-DI: 0853508002TD05UE			
PK1006 - NIM PAK NEEDLE- BEVEL	Class IIa		2023-07-31
PK1007 - NIM PAK NEEDLE- TROCAR	Class IIa		2023-07-31
PK1008 - NIM XPAK NEEDLE- BEVEL	Class IIa		2023-07-31
PK1009 - NIM XPAK NEEDLE- TROCAR	Class IIa		2023-07-31
PK1010 - NIM XPAK BLUNT	Class IIa		2023-07-31
PK1906 - NIM PAK NEEDLE- BEVEL, INTERNATIONAL	Class IIa		2023-07-31
PK1907 - NIM PAK NEEDLE- TROCAR, INTERNATIONAL	Class IIa		2023-07-31
PK1908 - NIM XPAK NEEDLE- BEVEL, INTERNATIONAL	Class IIa		2023-07-31
PK1909 - NIM XPAK NEEDLE- TROCAR, INTERNATIONAL	Class IIa		2023-07-31
PK1910 - NIM XPAK BLUNT, INTERNATIONAL	Class IIa		2023-07-31

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620146584-04
Product list issue date: 17 January 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Basic UDI-DI: 0853508002TD06UG			
PK1013 - NIM PEDICLE PROBE - THORACIC	Class IIa		2023-07-31
PK1014 - NIM PEDICLE PROBE - LUMBAR	Class IIa		2023-07-31
PK1015 - NIM PEDICLE PROBE - STRAIGHT	Class IIa		2023-07-31
PK1913 - NIM PEDICLE PROBE - THORACIC, INTERNATIONAL	Class IIa		2023-07-31
PK1914 - NIM PEDICLE PROBE - LUMBAR, INTERNATIONAL	Class IIa		2023-07-31
PK1915 - NIM PEDICLE PROBE - STRAIGHT, INTERNATIONAL	Class IIa		2023-07-31
Basic UDI-DI: 0853508002TD07UJ			
PK1911 - NAV PAK NEEDLE- TROCAR, INTERNATIONAL	Class IIa		2023-07-31
PK1912 - NIM NAV PAK NEEDLE- TROCAR, INTERNATIONAL	Class IIa		2023-07-31

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