



EC REPRESENTATIVE CERTIFICATE

This is to Certify That, We **Maxcert Germany** acts as EU Authorized Representative for the mentioned manufacturer and agree to perform the duties and responsibilities as the EC REP according to the MDD 93/42/EEC as amended by 2007/47/EC

Certificate Number: **MCE/2022/0002037-2**
Manufacturer Name: **Darleys Surgical Co.**
Company Address: **2-A Kutchery Road, Slalkot-51310, Pakistan**
Product Type & Class: **Meet the essential requirement of Medical Device Directive 93/42/EEC as amended by 2007/47/EC and falls within manufacturers of Class – I devices (Annex A- Product List)**
EUDAMED Registration: **PK-MF-000034544**

The manufacturer has ensured to provide us with an appropriate technical documentation and declaration of conformity for the mentioned products (list of products see annex 1)

The certificate remains valid until the expiration agreement of EC REP, renewed annually, unless manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

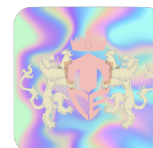
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Issued on: **18/03/2024**

Surveillance Audit until: **17/03/2025**



DE/000005001
BfArM Germany



To Verify this certificate,
scan the QR code & check
EUDAMED database

Authorized Signatory Certification
MAXCERT EC REPRESENTATIVE

This certificate remains the property of Maxcert to whom must be returned when asked and can be withdrawn without notice. Actual EC Rep status can be confirmed from EUDAMED database. This certificate is for the exclusive use of Maxcert's client and is provided as proof of Authorized Representation after the agreement (Mandate) between Maxcert and the client. Maxcert assumes no liability to any loss, expense or damage occurred by the use of this certificate and the Authorized Representative agreement (Mandate). The provided SRN can be verified from EUDAMED database.

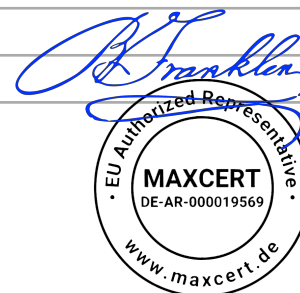
MAXCERT EUREP
Heidelbergerstr 79, 69190 Walldorf Germany
EC-REPRESENTATIVE (SRN# DE-AR-000019569)
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ANNEX-1: Product List (Page 2-3) All Class 1

GMDNS Code	Device Name
62467	Surgical soft-tissue manipulation forceps, alligator, reusable
62468	Surgical soft-tissue manipulation forceps, scissors-like, reusable
62466	Surgical soft-tissue manipulation forceps, tweezers-like, reusable
12143	Instrument Tray
35131	Amputation knife
13481	Bandage scissors, reusable
38727	General-purpose surgical scissors, reusable
45414	Liposuction cannula, reusable
62727	Skin marking guide, reusable
46773	Fibreoptic retractor handle
11791	Dressing/utility forceps, scissors-like, reusable
42500	Dressing/utility forceps, tweezers-like, reusable
42367	Scleral marker, reusable
42468	Clamp manipulation forceps
12726	Needle Holder, reusable
12235	Scalpel handle, reusable
32382	Scalpel, reusable
45726	Medicine cup, reusable
11799	Forceps jar
35559	Bone file/rasp, manual
35013	Periodontal file/rasp, manual
12844	Orthopaedic osteotome
10825	Orthopaedic chisel



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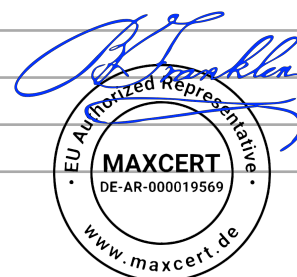
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ANNEX-1: Product List (Page 3-3)

GMDNS Code	Device Name
45918	Hand-held surgical retractor, reusable
45182	Self-retaining surgical retractor, reusable
42893	General-purpose bowl, reusable
13730	Sterilization/disinfection container
32312	Surgical mallet
35085	Mouth gag, adjustable, reusable
35090	Surgical gouge
64314	Dental sinus lift elevator
38168	Periosteal elevator, reusable
11290	Open-surgery dissector
38797	Dermatome, manual
35350	Nasal speculum, reusable
35349	Eyelid speculum, reusable
35352	Vaginal speculum, reusable
35351	Rectal speculum
15076	Rigid intubation laryngoscope, reusable
12849	Otoscope, direct
46786	Direct ophthalmoscope, battery-powered
32659	Fetal stethoscope
16341	Cast cutting shears
44445	Cast/plaster saw
62558	General-purpose curette
32853	Orthopaedic joint/limb rongeur
36235	Surgical hand drill
36293	Abdominal/intestinal spatula
36199	Adenoid punch forceps
11775	Open-surgery biopsy forceps, reusable



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