

EU DECLARATION OF CONFORMITY / DEKLARACJA ZGODNOŚCI UE

Manufacturer / Producent: **Grena (Qingdao) Medical Devices Ltd.,**
No 318 Huanghe West Road, Huangdao District,
Qingdao City, Shandong Province,
266555 China

SRN: CN-MF-000009861

**Authorized representative /
Upoważniony przedstawiciel:** **MDML Intl Limited**
10 McCurtain Hill Clonakilty,
Co. Cork, P85 K230,
Republic of Ireland

SRN: IE-AR-000001156

Basic UDI-DI: 697269668046R5

Product / Produkt: Connecting tube (non-sterile) / Dren łączący (niesterylny)

EMDN code / Kod EMDN: A060102 SURGICAL DRAINAGE CONNECTION MEDICAL TUBES

REF number(s) / Numer(y) REF: See List of Connecting tube (non-sterile) / Patrz- Lista Drenów łączących (niesterylnych)

**Product intended purpose /
Przewidziane zastosowanie
wyrobu:** Connecting tubes and connectors are used in surgery, internal medicine,
gynaecology, bariatric medicine and paediatrics to connect:

1. suction cannula with suction source.
2. suction catheter with suction source.
3. drainage catheters with collection chambers.
4. other medical devices with each other to transport gases or fluids. /

Dreny łączące i łączniki są stosowane w chirurgii, medycynie wewnętrznej,
ginekologii, medycynie bariatrycznej i pediatrii do łączenia:

1. kaniuli ssącej ze źródłem ssania.
2. cewnika ssącego ze źródłem ssania.
3. cewników drenażowych z komorami zbiorczymi.
4. innych urządzeń medycznych w celu transportu gazów lub płynów.

Classification / Klasyfikacja: Class I, rule 1 according to Annex VIII of the MDR (EU) 2017/745 /
Klasa I, reguła 1 zgodnie z załącznikiem VIII do MDR (UE) 2017/745

**Reference to common
specification / Odniesienie do
wspólnej specyfikacji:** NA

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 concerning medical devices which apply to them. We declare the conformity of the product by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III of the Regulation. All supporting documentation is retained under the premises of the manufacturer. /

Niniejszym oświadczamy na naszą wyłączną odpowiedzialność, że wyżej wymienione produkty spełniają przepisy ROZPORZĄDZENIA (UE) 2017/745 w sprawie wyrobów medycznych, które mają do nich zastosowanie. Deklarujemy zgodność produktu poprzez wystawienie deklaracji zgodności UE, o której mowa w art. 19, po sporządzeniu dokumentacji technicznej określonej w załącznikach II i III do rozporządzenia. Cała dokumentacja uzupełniająca przechowywana jest w siedzibie producenta.

**Notified body / Jednostka
notyfikowana:** NA
**EU certificate number / Numer
certyfikatu UE:** NA

Qingdao, 2023-11-07

(place & date) /

(miejsce i data)

Wang Jinmei



General manager (signature) / Dyrektor generalny (podpis)

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List of Connecting tube (non-sterile) / Lista Drenów łączących (niesterylnych)

| Ref number / Numer ref. | Description / Opis |
|-------------------------|---|
| 0201-B3005 | Connecting Tube, bubble, 30mx5mm, 1 pc, non-sterile |
| 0201-B3006 | Connecting Tube, bubble, 30mx6mm, 1 pc, non-sterile |
| 0201-B3007 | Connecting Tube, bubble, 30mx7mm, 1 pc, non-sterile |
| 0201-B3008 | Connecting Tube, bubble, 30mx8mm, 1 pc, non-sterile |
| 0201-C3007090 | Connecting Tube, cut-off, 30mx7mmx90cm, non-sterile |
| 0201-C3007180 | Connecting Tube, cut-off, 30mx7mmx180cm, non-sterile |
| 0201-C5005090 | Connecting Tube, cut-off, 50mx5mmx90cm, non-sterile |
| 0201-C5005180 | Connecting Tube, cut-off, 50mx5mmx180cm, non-sterile |
| 0201-C5006090 | Connecting Tube, cut-off, 50mx6mmx90cm, non-sterile |
| 0201-C5006180 | Connecting Tube, cut-off, 50mx6mmx180cm, non-sterile |
| 0201-10007SSNS | Connecting Tube, 100x7, 2 small female connectors + cap, non-sterile |
| 0201-18005LCNS | Connecting Tube, 180x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-18005LLNS | Connecting Tube, 180x5, 2 large female connectors, non-sterile |
| 0201-18005SCNS | Connecting Tube, 180x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-18005SLNS | Connecting Tube, 180x5, 1 small, 1 large female connector, non-sterile |
| 0201-18005SSNS | Connecting Tube, 180x5, 2 small female connectors + cap, non-sterile |
| 0201-18005SSPNS | Connecting Tube, 180x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-18005SSVSNS | Connecting Tube, 180x5, 1 small female, 1 vacu stop, non-sterile |
| 0201-18005STNS | Connecting Tube, 180x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-18006LCNS | Conneting tube, 180x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-18006LLNS | Conneting tube, 180x6, 2 large female connectors, non-sterile |
| 0201-18006SCNS | Conneting tube, 180x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-18006SLNS | Conneting tube, 180x6, 1 small, 1 large female connectors, non-sterile |
| 0201-18006SSNS | Conneting tube, 180x6, 2 small female connectors + cap, non-sterile |
| 0201-18006SSPNS | Conneting tube, 180x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-18006SSVSNS | Conneting tube, 180x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-18006STNS | Conneting tube, 180x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-18007LCNS | Conneting tube, 180x7, 1 large female, 1 catheter connectors, non-sterile |
| 0201-18007LLNS | Conneting tube, 180x7, 2 large female connectors, non-sterile |
| 0201-18007SCNS | Conneting tube, 180x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-18007SLNS | Conneting tube, 180x7, 1 small, 1 large female connectors, non-sterile |
| 0201-18007SSNS | Conneting tube, 180x7, 2 small female connectors + cap, non-sterile |
| 0201-18007SSPNS | Conneting tube, 180x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-18007SSVSNS | Conneting tube, 180x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-18007STNS | Conneting tube, 180x7, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-20005LCNS | Conneting tube, 200x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-20005LLNS | Conneting tube, 200x5, 2 large female connectors, non-sterile |

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| 0201-20005SCNS | Conneting tube, 200x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-20005SLNS | Conneting tube, 200x5, 1 small, 1 large female connectors, non-sterile |
| 0201-20005SSNS | Conneting tube, 200x5, 2 small female connectors + cap, non-sterile |
| 0201-20005SSPNS | Conneting tube, 200x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-20005SSVSNS | Conneting tube, 200x5, 1 small female, 1 vacu stop, non-sterile |
| 0201-20005STNS | Conneting tube, 200x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-20006LCNS | Conneting tube, 200x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-20006LLNS | Conneting tube, 200x6, 2 large female connectors, non-sterile |
| 0201-20006SCNS | Conneting tube, 200x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-20006SLNS | Conneting tube, 200x6, 1 small, 1 large female connectors, non-sterile |
| 0201-20006SSNS | Conneting tube, 200x6, 2 small female connectors + cap, non-sterile |
| 0201-20006SSPNS | Conneting tube, 200x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-20006SSVSNS | Conneting tube, 200x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-20006STNS | Conneting tube, 200x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-20007LCNS | Conneting tube, 200x7, 1 large female, 1 catheter connectors, non-sterile |
| 0201-20007LLNS | Conneting tube, 200x7, 2 large female connectors, non-sterile |
| 0201-20007SCNS | Conneting tube, 200x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-20007SLNS | Conneting tube, 200x7, 1 small, 1 large female connectors, non-sterile |
| 0201-20007SSNS | Conneting tube, 200x7, 2 small female connectors + cap, non-sterile |
| 0201-20007SSPNS | Conneting tube, 200x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-20007SSVSNS | Conneting tube, 200x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-20007STNS | Conneting tube, 200x7, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-20008SSNS | Connecting Tube, 200x8, 2 small female connectors + cap, non-sterile |
| 0201-21005LCNS | Conneting tube, 210x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-21005LLNS | Conneting tube, 210x5, 2 large female connectors, non-sterile |
| 0201-21005SCNS | Conneting tube, 210x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-21005SLNS | Conneting tube, 210x5, 1 small, 1 large female connectors, non-sterile |
| 0201-21005SSNS | Conneting tube, 210x5, 2 small female connectors + cap, non-sterile |
| 0201-21005SSPNS | Conneting tube, 210x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-21005SSVSNS | Conneting tube, 210x5, 1 small female, 1 vacu stop, non-sterile |
| 0201-21005STNS | Conneting tube, 210x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-21006LCNS | Conneting tube, 210x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-21006LLNS | Conneting tube, 210x6, 2 large female connectors, non-sterile |
| 0201-21006SCNS | Conneting tube, 210x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-21006SLNS | Conneting tube, 210x6, 1 small, 1 large female connectors, non-sterile |
| 0201-21006SSNS | Conneting tube, 210x6, 2 small female connectors + cap, non-sterile |
| 0201-21006SSPNS | Conneting tube, 210x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-21006SSVSNS | Conneting tube, 210x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-21006STNS | Conneting tube, 210x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-21007LCNS | Conneting tube, 210x7, 1 large female, 1 catheter connectors, non-sterile |

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| 0201-21007LLNS | Conneting tube, 210x7, 2 large female connectors, non-sterile |
| 0201-21007SCNS | Conneting tube, 210x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-21007SLNS | Conneting tube, 210x7, 1 small, 1 large female connectors, non-sterile |
| 0201-21007SSNS | Conneting tube, 210x7, 2 small female connectors + cap, non-sterile |
| 0201-21007SSPNS | Conneting tube, 210x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-21007SSVSNS | Conneting tube, 210x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-21007STNS | Conneting tube, 210x7, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-23007SSNS | Connecting Tube, 230x7, 2 small female connectors + cap, non-sterile |
| 0201-30005LCNS | Conneting tube, 300x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-30005LLNS | Conneting tube, 300x5, 2 large female connectors, non-sterile |
| 0201-30005SCNS | Conneting tube, 300x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-30005SLNS | Conneting tube, 300x5, 1 small, 1 large female connectors, non-sterile |
| 0201-30005SSNS | Conneting tube, 300x5, 2 small female connectors + cap, non-sterile |
| 0201-30005SSPNS | Conneting tube, 300x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-30005SSVSNS | Conneting tube, 300x5, 1 small female, 1 vacu stop, non-sterile |
| 0201-30005STNS | Conneting tube, 300x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-30006LCNS | Conneting tube, 300x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-30006LLNS | Conneting tube, 300x6, 2 large female connectors, non-sterile |
| 0201-30006SCNS | Conneting tube, 300x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-30006SLNS | Conneting tube, 300x6, 1 small, 1 large female connectors, non-sterile |
| 0201-30006SSNS | Conneting tube, 300x6, 2 small female connectors + cap, non-sterile |
| 0201-30006SSPNS | Conneting tube, 300x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-30006SSVSNS | Conneting tube, 300x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-30006STNS | Conneting tube, 300x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-30007LCNS | Conneting tube, 300x7, 1 large female, 1 catheter connectors, non-sterile |
| 0201-30007LLNS | Conneting tube, 300x7, 2 large female connectors, non-sterile |
| 0201-30007SCNS | Conneting tube, 300x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-30007SLNS | Conneting tube, 300x7, 1 small, 1 large female connectors, non-sterile |
| 0201-30007SSNS | Conneting tube, 300x7, 2 small female connectors + cap, non-sterile |
| 0201-30007SSPNS | Conneting tube, 300x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-30007SSVSNS | Conneting tube, 300x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-30007STNS | Conneting tube, 300x7, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-33007SSNS | Connecting Tube, 330x7, 2 small female connectors + cap, non-sterile |
| 0201-35005LCNS | Conneting tube, 350x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-35005LLNS | Conneting tube, 350x5, 2 large female connectors, non-sterile |
| 0201-35005SCNS | Conneting tube, 350x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-35005SLNS | Conneting tube, 350x5, 1 small, 1 large female connectors, non-sterile |
| 0201-35005SSNS | Conneting tube, 350x5, 2 small female connectors + cap, non-sterile |
| 0201-35005SSPNS | Conneting tube, 350x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-35005SSVSNS | Conneting tube, 350x5, 1 small female, 1 vacu stop, non-sterile |

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| 0201-35005STNS | Conneting tube, 350x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-35006LCNS | Conneting tube, 350x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-35006LLNS | Conneting tube, 350x6, 2 large female connectors, non-sterile |
| 0201-35006SCNS | Conneting tube, 350x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-35006SLNS | Conneting tube, 350x6, 1 small, 1 large female connectors, non-sterile |
| 0201-35006SSNS | Conneting tube, 350x6, 2 small female connectors + cap, non-sterile |
| 0201-35006SSPNS | Conneting tube, 350x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-35006SSVSNS | Conneting tube, 350x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-35006STNS | Conneting tube, 350x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-35007LCNS | Conneting tube, 350x7, 1 large female, 1 catheter connectors, non-sterile |
| 0201-35007LLNS | Conneting tube, 350x7, 2 large female connectors, non-sterile |
| 0201-35007SCNS | Conneting tube, 350x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-35007SLNS | Conneting tube, 350x7, 1 small, 1 large female connectors, non-sterile |
| 0201-35007SSNS | Conneting tube, 350x7, 2 small female connectors + cap, non-sterile |
| 0201-35007SSPNS | Conneting tube, 350x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-35007SSVSNS | Conneting tube, 350x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-35007STNS | Conneting tube, 350x7, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-38005LCNS | Conneting tube, 380x5, 1 large female, 1 catheter connectors, non-sterile |
| 0201-38005LLNS | Conneting tube, 380x5, 2 large female connectors, non-sterile |
| 0201-38005SCNS | Conneting tube, 380x5, 1 small female, 1 catheter connectors, non-sterile |
| 0201-38005SLNS | Conneting tube, 380x5, 1 small, 1 large female connectors, non-sterile |
| 0201-38005SSNS | Conneting tube, 380x5, 2 small female connectors + cap, non-sterile |
| 0201-38005SSPNS | Conneting tube, 380x5, 1 small female, 1 small female +straight, non-sterile |
| 0201-38005SSVSNS | Conneting tube, 380x5, 1 small female, 1 vacu stop, non-sterile |
| 0201-38005STNS | Conneting tube, 380x5, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-38006LCNS | Conneting tube, 380x6, 1 large female, 1 catheter connectors, non-sterile |
| 0201-38006LLNS | Conneting tube, 380x6, 2 large female connectors, non-sterile |
| 0201-38006SCNS | Conneting tube, 380x6, 1 small female, 1 catheter connectors, non-sterile |
| 0201-38006SLNS | Conneting tube, 380x6, 1 small, 1 large female connectors, non-sterile |
| 0201-38006SSNS | Conneting tube, 380x6, 2 small female connectors + cap, non-sterile |
| 0201-38006SSPNS | Conneting tube, 380x6, 1 small female, 1 small female +straight, non-sterile |
| 0201-38006SSVSNS | Conneting tube, 380x6, 1 small female, 1 vacu stop, non-sterile |
| 0201-38006STNS | Conneting tube, 380x6, 1 small female, 1 taper connectors + cap, non-sterile |
| 0201-38007LCNS | Conneting tube, 380x7, 1 large female, 1 catheter connectors, non-sterile |
| 0201-38007LLNS | Conneting tube, 380x7, 2 large female connectors, non-sterile |
| 0201-38007SCNS | Conneting tube, 380x7, 1 small female, 1 catheter connectors, non-sterile |
| 0201-38007SLNS | Conneting tube, 380x7, 1 small, 1 large female connectors, non-sterile |
| 0201-38007SSNS | Conneting tube, 380x7, 2 small female connectors + cap, non-sterile |
| 0201-38007SSPNS | Conneting tube, 380x7, 1 small female, 1 small female +straight, non-sterile |
| 0201-38007SSVSNS | Conneting tube, 380x7, 1 small female, 1 vacu stop, non-sterile |
| 0201-38007STNS | Conneting tube, 380x7, 1 small female, 1 taper connectors + cap, non-sterile |