

# CE/MDR DOC

Model Name IPC Sleeve  
Doc. No. RND-R-DOC-110-01  
Rev. No. 1  
Rev. Date 2021.12.23



|                                                                                   |            |            |                  |
|-----------------------------------------------------------------------------------|------------|------------|------------------|
|  | CE/MDR DOC | Model Name | IPC Sleeve       |
|                                                                                   |            | Doc. No.   | RND-R-DOC-110-01 |
|                                                                                   |            | Rev. No.   | 1                |
|                                                                                   |            | Rev. Date  | 2021.12.23       |

## 0.1 Revision History

| Rev. No. | 일자 (Date)  | 내용 (Contents)                           | Prepared                                                                            | Reviewed                                                                            | Approved                                                                            |
|----------|------------|-----------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 0        | 2021.07.15 | First issued by application of MDR      |                                                                                     |                                                                                     |                                                                                     |
|          |            |                                         | 2021.07.15                                                                          | 2021.07.15                                                                          | 2021.07.15                                                                          |
| 1        | 2021.12.23 | Revision due to Basic UDI-DI correction |  |  |  |
|          |            |                                         | 2021.12.23                                                                          | 2021.12.23                                                                          | 2021.12.23                                                                          |
|          |            |                                         |                                                                                     |                                                                                     |                                                                                     |
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DAESUNG MAREF CO.,LTD.  
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Web Site : www.dsmaref.com

## *EU Declaration of Conformity*

**Manufacture is exclusively responsible for the declaration of conformity.**

**Manufacturer :**

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298-24, Gongdan-ro, Gunpo-Si, Gyeonggi-Do, Korea  
**SRN No. :** KR-MF-000008616

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**SRN No. :** DE-AR-000005685

**Device Name :** IPC Sleeve (EMDN Code : Z12069080)

**Model Name :** IPC Sleeve

**Classification :** Class I

**Device Name :** Tubing (EMDN Code : Z12069080)

**Model Name :** Tubing

**Classification :** Class I

**Basic UDI-DI - IPC Sleeve :** 880931567IPCSLEEVEZH

**Basic UDI-DI - Tubing :** 880931567TUBINGVL

| Category | Ref No. | Part Name                       | Remark |
|----------|---------|---------------------------------|--------|
|          | 4LAGL5A | LEG SLEEVE(L)                   |        |
|          | 4LAGX40 | LEG SLEEVE(XL)                  |        |
|          | 4LAGY00 | LEG SLEEVE(XXL)                 |        |
|          | 4AAGF3A | ARM SLEEVE(F)                   |        |
|          | 4SAGF5A | CENTER BODY SLEEVE(F)           |        |
|          | 4WAGF1A | WAIST SLEEVE(F)                 |        |
|          | 4MDRF00 | STRETCHING MAT 4(F)             |        |
|          | 4EAGF02 | ARM EXTENSION ZIPPER(F)         |        |
|          | 4ELGL02 | LEG EXTENSION ZIPPER(L)         |        |
|          | 4ELGX01 | LEG EXTENSION ZIPPER(XL)        |        |
|          | 4ELGY00 | LEG EXTENSION ZIPPER(XXL)       |        |
|          | 4ECGF01 | CENTER BODY EXTENSION ZIPPER(F) |        |
|          | S401    | OVERLAPPING LEG SLEEVE(S)       |        |
|          | SW401   | OVERLAPPING LEG SLEEVE(SW)      |        |
|          | SXW401  | OVERLAPPING LEG SLEEVE(SXW)     |        |
|          | M401    | OVERLAPPING LEG SLEEVE(M)       |        |
|          | MW401   | OVERLAPPING LEG SLEEVE(MW)      |        |
|          | MXW401  | OVERLAPPING LEG SLEEVE(MXW)     |        |
|          | L401    | OVERLAPPING LEG SLEEVE(L)       |        |

|        |         |                                 |  |
|--------|---------|---------------------------------|--|
| Sleeve | LW401   | OVERLAPPING LEG SLEEVE(LW)      |  |
|        | M403    | OVERLAPPING HALF-LEG SLEEVE(M)  |  |
|        | MW403   | OVERLAPPING HALF-LEG SLEEVE(MW) |  |
|        | M402    | OVERLAPPING ARM SLEEVE(M)       |  |
|        | L402    | OVERLAPPING ARM SLEEVE(L)       |  |
|        | 4VDRL00 | OVERLAPPING ARM CHEST SLEEVE(F) |  |
|        | 6LAGLA0 | LEG SLEEVE(L)                   |  |
|        | 6LAGLA1 | LEG SLEEVE(L)                   |  |
|        | 6LAGXA0 | LEG SLEEVE(XL)                  |  |
|        | 6LAGXA1 | LEG SLEEVE(XL)                  |  |
|        | 6LAGYA0 | LEG SLEEVE(XXL)                 |  |
|        | 6LAGYA1 | LEG SLEEVE(XXL)                 |  |
|        | 6AAGFA0 | ARM SLEEVE(F)                   |  |
|        | 6AAGFA1 | ARM SLEEVE(F)                   |  |
|        | 6WAGFA0 | WAIST SLEEVE(F)                 |  |
|        | 6WAGFA1 | WAIST SLEEVE(F)                 |  |
|        | 6PRGF01 | FULL BODY SLEEVE(F)             |  |
|        | 6EAGF30 | ARM EXTENSION ZIPPER(F)         |  |
|        | 6ELGL30 | LEG EXTENSION ZIPPER(L)         |  |
|        | 6ELGX30 | LEG EXTENSION ZIPPER(XL)        |  |
|        | 6ELGY30 | LEG EXTENSION ZIPPER(XXL)       |  |
| Tubing | 1000370 | SINGLE Tubing 2m                |  |
|        | 1000380 | DOUBLE Tubing 2m                |  |
|        | 100050A | DISTRIBUTION Tubing 0.5m        |  |
|        | 1000480 | SINGLE Tubing 2m                |  |

**Classification :**

The IPC Sleeve, Tubing are Class I device by Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017 ANNEX VIII Rule 1.

**Conformity Assessment Route :**

EU DECLARATION OF CONFORMITY following the ANNEX II + ANNEX III + Article 19 of Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards.

All supporting documentations are retained under the premises of the manufacture.

**Applied Standard**

IPC Sleeve, Tubing are conformity with essential requirement and Medical Devices Regulation 2017-745 of European Parliament and of the council of 5 April 2017.

EN/ISO 14971, EN 62366-1, EN/ISO 13485, EN/ISO 20417, EN/ISO 15223-1, EN/ISO 10993-1, EN/ISO 10993-5, EN/ISO 10993-10

Place of issue : KOREA

Date of issue : 23. Dec. 2021

Signature :



Jae Hwa Lee, CEO.  
On DAESUNG MAREF CO.,LTD.

## Attachments 1. S/N Information

Total Q'ty : 0

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