

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: Resuscitator and Accessories (Single use)

Medical Device: Manual Resuscitator, Pocket Size Resuscitator and accessories

Item Code: As Attachment

Classification: Ila


2460

according to Rule 2 in annex IX of directive 93/42/EEC

meets the provision of the directive 93/42/EEC in consideration of the change of the directive 2007/47/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 93/42/EEC annex II, excluding section 4; the manufacturer is fully responsible for the content of declaration of conformity.

Registration No.: 10240-2017-CE-RGC-NA-PS

Notified Body: DNV GL NEMKO PRESAFE AS (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse 71, 30855 Langenhagen, Germany

Taichung, May 24, 2019

Place / Date



Vice General Manager

Attachment of DoC

| Product Section | Product Reference codes |
|--------------------------|---|
| Manual Resuscitator | 60150 、 60151 、 60152 、 60144 、 60145 、 60146 、 60141 、 60142 、 60143 、 60121 、 60122 、 60123 、 60111 、 60112 、 60113 、 60101 、 60102 、 60103 、 60107 、 60108 |
| Accessories | 60013 、 60015 、 60017 、 60019 、 60021 、 60022 、 60023 、 60024 |
| Pocket Size Resuscitator | 30100 、 30101 、 30102 、 30103 、 30104 |

| Document title | | Declaration of conformity | |
|----------------|------------|---|-------------|
| Version: | Date | Revision History | Review by |
| 1 | 2019.1.31 | New release | Ariel Huang |
| 1.1 | 2019.05.24 | Update valid date and separate class I device | Phoebe Lu |