



Xi'an Bowa Industrial Automation Equipment Co., Ltd
Address: 3-10102A, East District, Modern Enterprise Center, Zhangba Road,
High-tech Zone, Xi'an, Shaanxi Province www.bowa-automation.com

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC) including Directive 2007/47/EC

Manufacturer Xi'an Bowa Industrial Automation Equipment Co, Ltd
Address: 3-10102A, East District Modern Enterprise Center, Zhangba Road, High-tech Zone, Xi'an, Shaanxi Province, China
Telephone: +86 2968590520 Facsimile number. +86 2968590520
EC Representative: Minerva Wise Limited
Address: Elite Business Centre, Trejqa ta' Box Box, Msida MSD1840 Malta Telephone: +356 23424214
Email: business@minervawiseltd.com
Product name: Medela Proximo Disposable Surgical Mask
Product name: Medela Proximo Disposable Medical Mask
Product name: Medela Kid Disposable Medical Mask
Model: 20202140022
Model: 20202140021
Model: 20202140023
Mode: Ear Loop

Classification: Class I
UMDNS code: 12447, 12458
Conformity Assessment Route: Annex VII
Clinical Evaluation: Annex X

We confirm our product can meet the requirement of Medical Device Directive (93/42/ EEC) and the following harmonized standards.

EN ISO 14683:2014 (Annex B&C)
EN ISO 14683:2019
EN ISO 22609:2004
EN ISO 14971:2012
EN ISO 15223-1:2016
EN ISO 1041 :2008+A1-2013
EN ISO 10993-1 :2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 11737:2006



Legal Representative
Mr. Yuanbo Zhao

03-04-2020