# *Declaration of Conformity*

CE 0123

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| ***Manufacturer's name :*** | Atom Medical Corporation |
| ***Manufacturer's address :*** | 18-15, Hongo 3-chome, Bunkyo-ku, Tokyo, 113-0033 Japan |
| ***Name of device :*** | Atom Infant Incubator Model 100 |
| ***Model :*** | Dual Incu i |
| ***Serial No. :*** | 191201272～ |
| ***Year of Manufacture :*** | 2020 |
| ***Classification :*** | Ⅱb, Rule 9 |
| ***Applied Standards :*** | |
| ・EN ISO 13485:2016/AC:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| ・EN ISO 14971:2012 | Medical devices - Application of risk management to medical devices |
| ・IEC 60601-1:2005/A1:2012 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| ・IEC 60601-1-2:2014 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| ・IEC 60601-1-6:2010/A1:2013 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| ・IEC 60601-1-8:2006/A1:2012 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| ・EN 60601-2-19:2009 | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators |
| ・EN 60601-2-21:2009 | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers |
| ・EN 62304:2006/AC:2008 | Medical device software - Software life cycle processes |
| ・EN 62366:2008 | Medical devices - Application of usability engineering to medical devices |
| ・ISO 10993-1:2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| ・ISO 9919:2005 | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |

# *Declaration of Conformity*

We under our sole responsibility, herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.
All supporting documentations are retained under the premises of the manufacturer and the notified body.

***This declaration is supported by :***

EC Certificate issued by TÜV SÜD Product Service GmbH in Ridlerstraße 65・80339 München, Germany.
Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC.
TÜV SÜD Product Service GmbH is Notified Body with identification no.0123

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***Date :*** Feb. 21, 2020

***Declared by :*** Tomoichi Kira

Tomoichi Kira
Quality Control Department Manager

***EC Representative :***

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