DECLARATION OF CONFORMITY

We hereby, **MEDEC International bv**, guarantee and declare that the CE Marked product as described, fulfill the applicable provisions of the Directive 93/42/EEC concerning medical devices, and are manufactured in conformity to EN ISO 13485 standards. An overview of the applicable harmonized standards is attached to this declaration.

Product Name: Anesthesia workstation

Model: **reference: 12032XXX Caelus**
Model: **reference: 12033XXX Caelus Lite**

Classification: class IIb according to Annex IX, rule 11

Global Medical Device Nomenclature Code (GMDN): 37710

This declaration is made on basis of the CE certificate, delivered by the Notified Body SZUTEST (Number 2195) in accordance with annex II (excluding section 4) of the Medical Device Directive 93/42/EEC.

This declaration is valid for all devices described here above, originating from the site at Wijngaardveld 14, 9300 Aalst, Belgium.

Date: 11/06/2020

BV MEDEC INTERNATIONAL
Wijngaardveld 14
B-9300 AALST
Phone 32 (0)53/70 35 44

Digitally signed by Bolea Petru
Date: 2022.12.14 10:26:11 EET
Reason: MoldSign Signature
Location: Moldova

Kristof Braem

CEO & Managing Director

Harmonised standards

Harmonized Standard	Application
MDD 93/42/EEC	Medical Device Directive
EN ISO 4135 : 2001	Anesthetic and respiratory equipment. Vocabulary
EN ISO 5356-1:2015	Anesthetic and respiratory equipment. Conical connectors. Cones and sockets
ISO 7000: 2019	Graphical symbols for use on equipment-index en synopsis
EN ISO 15223-1:2016	MD: Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 60601-1: 2014	Medical electrical equipment - part 1: General requirements for basic safety and essential performance
EN ISO 60601-1-2: 2007 & 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN IEC 60601-1-6: 2010	General requirements for basic and essential performance. usability
EN IEC 60601-1-8: 2012	General requirements for basic and essential performance. General requirements for tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
EN IEC 80601-2-26: 2019	Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph
EN IEC 80601-2-55: 2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 80601-2-13: 2012	Medical equipment. Particular requirements for the safety and essential performance of anesthetic systems.
EN 62304 : 2015	Medical device software life cycle process
IEC 62366: 2015	Medical devices – application of usability engineering to medical devices
EN ISO 10079-3 : 2014	Medical suction equipment. Suction equipment powered from a vacuum or pressure source
EN ISO 14155 : 2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971 : 2019	MD. Application of risk management to medical devices
EN ISO 10993-1 : 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
ISO 15001:2010	Anesthetic and respiratory equipment — Compatibility with oxygen

Medec International bv

Wijngaardveld 14
9300 Aalst – Belgium

sales@medec-intl.com
www.medec-intl.com

T +32 53 70 35 44
F +32 53 70 35 33

VAT BE 0727.935.906
IBAN BE75001864432451 BIC GEBABEBB