CE Declaration of Conformity

This is to confirm that, according to European Council Regulation (EU) 2017/745 Annexes II.3, Focus Instruments (SRN: FR-AR-000011522) performed the declaration duties and responsibilities as the European authorized representative of:

SAVEWO LIMITED
THE 1/F & 2/F, 266-270, TEXACO ROAD,
TSUEN WAN, N.T., HONG KONG SAR

The Manufacturer has provided Focus Instruments with the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Regulation EU MDR 2017/745.

According to European Council MDR (EU) 2017/745, the product classification is:

Disposable 3 Ply Earloop 3D Medical Face Mask

Class I Non-Sterile-rule 1 according to Annexes IX of MDR (EU) 2017/745
GMDN Code: 35177

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

EC Authorized Representative:

Focus Instruments
253, rue SAINT-HONORE
75001 Paris, France

Authorized Signatory:

Regulatory Manager

Place:
253，rue SAINT-HONORE，75001 Paris

Renewal Date:
31 Jan, 2024

Validity Date Until 31 Dec 2024

This document will become invalid once the notification status changed of the EU agreement is terminated.

REF: APP00000978922/24-1-HK

EU DECLARATION OF CONFORMITY

EU Regulation 2016/425

This is to confirm that, according to EU Regulation 2016/425, Focus Instruments (SRN: FR-AR-000011522) performed the registration duties and responsibilities as the European authorized representative of:

SAVEWO LIMITED

THE 1/F & 2/F, 266-270, TEXACO ROAD,
TSUEN WAN, N.T., HONG KONG SAR

The Manufacturer has provided Focus Instruments with the EC Declaration of Conformity confirming that the personal protective equipment, as stipulated here below, is fulfilling the applicable requirements of the EU Regulation 2016/425, EN149:2001+A1:2009.

According to Regulation (EU) 2016/425, the product classification is:

Particulate Respirator (FFP2 & FFP3)

According to EU type-examination for Regulation (EU) 2016/425 Module D
Product Name: SAVEWO 3DMASK (Model: 3D3PH, 3D5PX, Smile);
SAVEWO ROYALMASK (Model: RM, RM-Pro)

on the basis that SGS (Notified Body Number 0598), performed the relevant Type Examination procedures under the requirement with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Article 10 of PPE Directive 89/686/EEC (Module D) and with the National Standard of harmonized standard EN 149:2001 + A1:2009.

EC Representative:

Focus Instruments
253, rue SAINT-HONORE
75001 Paris, France

Authorized Signatory:

Regulatory Manager

Place: 253，rue SAINT-HONORE，75001 Paris

Renewal Date: 31 Jan, 2024

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