REF: APP000009789-SW

EU DECLARATION OF CONFORMITY

This is to confirm that, according to EU Regulation 2016/425, Focus Instruments performed the registration duties and responsibilities as the European authorized representative of:

SAVEWO LIMITED

FLAT B1, 10/F, BLOCK B, YEE LIM INDUSTRIAL CENTRE, 2-28 KWAI LOK STREET, KWAI CHUNG, NT / THE FIRST FLOOR, 266-270, TEXACO ROAD, TSUEN WAN, NT. 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 NR)
According to EU type-examination for Regulation (EU) 2016/425
Product Name: SAVEWO ULTRA, KURO (Model 3D3PH)

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) Annex V & VII (Module B & C2) 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:

	Place	Date
International Manager	253，rue SAINT-HONORE，75001 Paris	12 June , 2021

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

Registered at: ASNM - The National Agency for the Safety of Medicines and Health, France

CE Declaration of Conformity

This is to confirm that, according to council directive MDD 93/42/EEC Annex II.3, Focus Instruments performed the declaration duties and responsibilities as the European authorized representative of:

SAVEWO LIMITED

FLAT B1, 10/F, BLOCK B, YEE LIM INDUSTRIAL CENTRE, 2-28 KWAI LOK STREET, KWAI CHUNG, NT / THE FIRST FLOOR, 266-270, TEXACO ROAD, TSUEN WAN, NT

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 Directive 93/42/EEC.

According to MDD 93/42/EEC of 14 June, 1993 as amended, the product classification is:

Disposable 3 Ply Earloop Medical Face Mask

Class I Non-Sterile-rule 1 according to Annex IX of 93/42/EEC

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 Representative:

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

Authorized Signatory:

International Manager	253，rue SAINT-HONORE，75001 Paris Place	Aug 28, 2020 Date

Ref: swdoc28082020

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Registered at: ANSM - The National Agency for the Safety of Medicines and Health, France

Ref. DM1SM202000604

CE Declaration of Conformity

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

SAVEWO LIMITED

FLAT B1, 10/F, BLOCK B, YEE LIM INDUSTRIAL CENTRE, 2-28 KWAI LOK STREET, KWAI CHUNG, NT / THE FIRST FLOOR, 266-270, TEXACO ROAD, TSUEN WAN, NT

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 Insruments
253, rue SAINT-HONORE
75001 Paris, France

Authorized Signatory:

Zheng

International Manager

Place: 253，rue SAINT-HONORE，75001 Paris

Date of Issue: 28 May, 2021

Expired Date: 28 May 2022

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