EU DECLARATION OF CONFORMITY

The Manufacturer of the product covered by this Declaration is:

Dymedso Inc., 2120, 32nd Avenue, Montreal (Quebec) Canada H8T 3H7

Phone: +1 514-636-9959, Fax: +1 514-631-9959, Email: info@dymedso.com

The EU Authorized Representative is:

Arazy Group GmbH, Am Kalkofen 8, 61206 Wöllstadt, Germany

Phone: +49 60 34 90 59 49 – 0
Fax: +49 60 34 90 59 49 – 9

The product covered by this Declaration:

Product Name: Frequencer

Model: V2/V2x (V2.3)

Description: Airway Clearance Device

Equipment Type: Medical Electrical Equipment

Serial Number(s): 2018Q130182-30183-30184-30185-30186-30187-30189-30190

Manufacturing Date: 2018

EU Device Classification: Class IIa Conformity Route: Annex V

The Notified Body is:

Intertek SEMKO AB. (# 0413)

Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden

Phone +46 8 750 00 00

The Directives covered by the declaration

Council Directive 2014/30/EU (February 2014) – Electromagnetic Compatibility

Council Directive 93/42/EEC (June 1993) – Medical Devices

Council Directive 2007/47/EC (September 2007) – Regulation amending MDD 93/42/EEC

Council Directive 93/68/EEC (July 1993) – CE Marking Directive

Council Directive 2006/95/EC (December 2006) – Low Voltage Directive

Council Directive 2011/65/EU (June 2011) – RoHS 2

The technical documentation required to demonstrate that the products meet the requirements of the above mentioned Council Directives has been compiled and is available for inspection by the relevant authorities.

The CE Mark was applied in 2018.

Signature: _____

Yvon Robert

Position: President and CEO

Place/Date: Montreal (Quebec) Canada 2018-08-29