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## EC – Declaration of Conformity

**Basic UDI Nr:** 8720589543UZ/MEDQV

**Date Document:** 2/06/2021

**The manufacturer or his authorized representative:** UltraZonic, as manufacturer of pre-cleaning devices for endoscopes and ultrasonic pre-cleaning devices for surgical instruments

**Address:** Boutersemdreef 26, 2240 Zandhoven, Belgium

**Single registration number (SRN):** APP000008401

**Declares under his sole responsibility that the CE marked devices:**

Generic Name: MED

Type Number (22): UZ/MED WWXXYY ZZZ

Serial Number (21): UZMEDMMYYXXX

Intended Purpose: semi-automated pre-cleaning devices for surgical instruments

**have been classified as class I, according to annex VIII (EU) MDR 2017/745, rule 13,**

**and is manufactured in full conformity with the European instructions below - including the latest modifications - and with the national law, that organizes this directions:**

Medical devices directive MDR 2017/745 Annex VIII

**and is in conformity with the relevant European harmonized standards:**

- **DIRECTIVE 2006/42/EG of the EUROPEAN PARLIAMENT and COMMISSION d.d. 17 May 2006 regarding machines**
- **DIRECTIVE 2014/30/EG of the EUROPEAN PARLIAMENT and COMMISSION d.d. 26 February 2014 regarding internal conformity of the legislation regarding electromagnetical compatibility**
- **DIRECTIVE 2014/35/EG of the EUROPEAN PARLIAMENT and COMMISSION d.d. 26 February 2014 regarding internal conformity of the legislation regarding electrical devices used within defined tensions.**

And declares that (parts of) existing harmonised standards apply:

- **NBN – EN ISO12100-1**
- **NBN – EN ISO 12100-2**
- **NBN – EN 60204-1**
- **NBN – EN 13857**

**City, Date:** Zandhoven, 2/06/2021

**Signature:**

A handwritten signature in blue ink, appearing to be "Nancy Steenbakkers", written over a horizontal line.

**Function, Name:** Founder & CEO: Nancy Steenbakkers