



EC – Declaration of Conformity

Basic UDI Nr: 8720589543UZ/ENDO4G

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: ENDO

Type Number (22): UZ/ENDO WW-XX-YY-ZZZ

Serial Number (21): UZENDOMMYXXX

Intended Purpose: semi-automated pre-cleaning of flexible endoscopes

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.**

City, Date: Zandhoven, 2/06/2021

Signature:

A handwritten signature in blue ink, appearing to be "AS", written over a faint circular stamp or watermark.

Function, Name: Founder & CEO: Nancy Steenbakkens