

	ISS AC-575 Series - DoC		Date:	2021.05.10
			Page:	1 / 1
	Document ID:	SOP-0042-5	Ver.:	v.02.0
Q:\Quality File\10. Documentation Handling\Celitron SOP\SOP-0042-5 v.02.0 - ISS-575 DoC - Product.docx				

Manufacturer: Celitron Medical Technologies Kft.
Address: H-2600 Vác, Szent László út 36.
Product: Integrated Steam Sterilizer and Shredder
Model Code: ISS 150; ISS AC-575; ISS AC-575DD and ISS AC-575 Premium
Serial Number: 46 YY SSSS

Celitron Medical Technologies Kft. Hungary hereby declares under its sole responsibility that the Machine and its variations identified above comply with the appropriate essential safety and health requirements of the EC Directive, with protection requirements of the EMC directive and with the principal elements of the safety objectives of the Low Voltage Equipment directive.

The technical documentation required to demonstrate that the products meet the requirements of the Machinery Directive, EMC Directive and Low Voltage Equipment directive has been compiled and is held on EU territory available for inspection by the relevant enforcement authorities and can be made available to the relevant authorities within a reasonable period.

The CE mark was first applied in 2010

General Applicable Directives:

- Machinery Directive – 2006/42/EC
- Pressure Equipment Directive – 2014/68/EU
- Electromagnetic Compatibility Directive – 2014/30/EU
- RoHS II Directive – 2011/65/EU

General Applicable Standards:

- IEC 60204-1:2016 – Safety of machinery. Electrical equipment of machines. Part 1: General requirement
- IEC 61000-6-2:2016 – Electromagnetic compatibility (EMC). Part 6-2: Generic standards. Immunity standard for industrial environments
- IEC 61000-6-3:2006 – Electromagnetic compatibility (EMC). Part 6-3: Generic standards. Emission standard for residential, commercial and light-industrial environments
- IEC 61000-6-4:2018 – Electromagnetic compatibility (EMC). Part 6-4: Generic standards. Emission standard for industrial environments



 Zsolt Plachi
 Quality Assurance Manager, Management Representative

CELITRON MEDICAL
 TECHNOLOGIES KFT.
 2600 Vác, Szent László út 36.
 Adószám: 13552710-2-13

 2021.06.16
 Place and date

Attention!

The attention of the specifier, purchaser, installer, or user is drawn to special measures and limitations to use that must be observed when these products are taken into service to maintain compliance with the above directives. Details of special measures and limitations to use are available on request and are contained in the product manuals.

