celitron WE THINK GREEN!	Declaration of Conformity – Sting 11		Date:	2022.08.10
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	Document ID:	SOP-0042-1	Ver.:	v.01.7
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Manufacturer: Celitron Medical Technologies Kft.
Address: H-2600 Vác, Szent László út 36.
Product: Bench Top Steam Sterilizer
Model Code: Sting 11
Classification (MDD, Annex IX): IIb
Conformity Assessment Route: Annex II.3
EC- Certificate Number: 144998-20-04-30

Celitron Medical Technologies Kft. Hungary herewith declares under its sole responsibility that the above-mentioned products meet the provisions of the *Medical Device Directive MDD 93/42/EEC and Medical Device Regulation – MDR EU 2017/745 Article 120 (3).*
All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directives:

- *Medical Device Directive – MDD 93/42 EEC*
- *Medical Device Regulation – MDR EU 2017/745 Article 120 (3)*
- Pressure Equipment Directive- PED 2014/68/EU
- EMC Directive 2004/108/EC Article 7 (1)
- RoHS II Directive 2011/65/EU

General Applicable Standards:

- EN 61326-1:2013 - Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1: General requirements (IEC 61326-1:2012)
- EN 60601-1:2017 - Medical electrical equipment. Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
- EN 60601-1-2:2016 - Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests (IEC 60601-1-2:2014)
- EN 60601-1-6:2010 - Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability (IEC 60601-1-6:2010)
- EN 62366-1:2015 - Medical devices. Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)
- EN 1041:2008+A1:2014 - Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2017 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements (ISO 15223-1:2016; Corrected version 2017-03)
- EN 61010-1:2011 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements (IEC 61010-1:2010)
- EN 61010-2-040:2016 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)
- EN 13060:2014+A1:2019 - Small steam sterilizers

Notified Body:

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering, Hungary, H-2092 Budakeszi, Erdő utca 101.

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

Vác 08/09/2022

Management Representative

Place and date

Digitally signed by Botnaru Andrei
Date: 2022.09.15 11:05:56 EEST
Reason: MoldSign Signature
Location: Moldova

CE 2409

celitron WE THINK GREEN!	Declaration of Conformity – Azteca A-Series		Date:	2022.03.11
			Page:	1 / 1
	Document ID:	SOP-0042-2	Ver.:	v.01.6
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Manufacturer: Celitron Medical Technologies Kft.
Address: H-2600 Vác, Szent László út 36.
Product: Standalone Large Steam Sterilizer
Model Code: Azteca A-Series
Classification (MDD, Annex IX): IIb
Conformity Assessment Route: Annex II.3
EC- Certificate Number: 144998-20-04-30

Celitron Medical Technologies Kft. Hungary herewith declares under its sole responsibility that the above-mentioned products meet the provisions of the *Medical Device Directive MDD 93/42/EEC and Medical Device Regulation – MDR EU 2017/745 Article 120 (3).* All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directives:

- *Medical Device Directive – MDD 93/42 EEC*
- *Medical Device Regulation – MDR EU 2017/745 Article 120 (3)*
- Pressure Equipment Directive- PED 2014/68/EU
- EMC Directive 2004/108/EC Article 7 (1)
- RoHS II Directive 2011/65/EU

General Applicable Standards:

- 47CFR part 15: 2004, subpart B, Class A;
- EN 61326-1:2013 - Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1: General requirements (IEC 61326-1:2012)
- EN 60601-1:2017 - Medical electrical equipment. Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
- EN 60601-1-2:2016 - Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests (IEC 60601-1-2:2014)
- EN 60601-1-6:2010 - Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability (IEC 60601-1-6:2010)
- EN 62366-1:2015 - Medical devices. Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)
- EN 1041:2008+A1:2014 - Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2017 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements (ISO 15223-1:2016; Corrected version 2017-03)
- EN 61010-1:2011 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements (IEC 61010-1:2010)
- EN 61010-2-040:2016 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)
- EN 285:2016 - Sterilization. Steam sterilizers. Large sterilizers

Notified Body:

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering, Hungary, H-2092 Budakeszi, Erdő utca 101.

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

Vonga Anita Katalin

Management Representative

Vác 08/09/2022

Place and date

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celitron WE THINK GREEN!	**Declaration of Conformity – Azteca AC-Series**	**Date:**	2022.03.16
		Page:	1 / 1
	Document ID: SOP-0042-3	**Ver.:**	v.01.3
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Manufacturer: Celitron Medical Technologies Kft.
Address: H-2600 Vác, Szent László út 36.
Product: Bench Top Steam Sterilizer
Model Code: Azteca AC-Series
Classification (MDD, Annex IX): IIb
Conformity Assessment Route: Annex II.3
EC- Certificate Number: 144998-20-04-30

Celitron Medical Technologies Kft. Hungary herewith declares under its sole responsibility that the above-mentioned products meet the provisions of the *Medical Device Directive MDD 93/42/EEC and Medical Device Regulation – MDR EU 2017/745 Article 120 (3).* All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directives:

- *Medical Device Directive – MDD 93/42 EEC*
- *Medical Device Regulation – MDR EU 2017/745 Article 120 (3)*
- Pressure Equipment Directive- PED 2014/68/EU
- EMC Directive 2004/108/EC Article 7 (1)
- RoHS II Directive 2011/65/EU

General Applicable Standards:

- 47CFR part 15: 2004, subpart B, Class A;
- EN 61326-1:2013 - Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1: General requirements (IEC 61326-1:2012)
- EN 60601-1:2017 - Medical electrical equipment. Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
- EN 60601-1-2:2016 - Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests (IEC 60601-1-2:2014)
- EN 60601-1-6:2010 - Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability (IEC 60601-1-6:2010)
- EN 62366-1:2015 - Medical devices. Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)
- EN 1041:2008+A1:2014 - Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2017 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements (ISO 15223-1:2016; Corrected version 2017-03)
- EN 61010-1:2011 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements (IEC 61010-1:2010)
- EN 61010-2-040:2016 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2015)
- EN 285:2016 - Sterilization. Steam sterilizers. Large sterilizers

Notified Body:

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering, Hungary, H-2092 Budakeszi, Erdő utca 101.

CELITRON MEDI...
TECHNOLOGIES KF...
2600 Vác, Szent László út ...
Adószám: 13552710-2-...

Varga Anita Katalin

Management Representative

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Place and date

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