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for pathology

Declaration of Conformity

We herewith declare, in exclusive responsibility, that the instrument

Linear Stainer Cromatec I & II

UDI-DI.: 4260248680266WR

Reg. No.: DE/CA72/00114832

are developed, designed and manufactured in compliance with the applicable directives

- **Council Directive 2014/35/EU, (Low Voltage) and**
- **Council Directive 2014/30/EU (Electromagnetic Compatibility)**
- **Risk Management ISO 14971:2019**
- **IVDR (EU) 2017/746 – Class "Risk class "A" / Annex VIII – Rule V – Classification. These are instruments specifically intended for use in in vitro diagnostic procedures. laboratory supplies without critical features intended to make the products usable for in vitro diagnostic procedures in connection with a specific investigation's medical devices Technical documentation Annex II & Post-Market Surveillance Annex III**
- **Directive 2011/65/EU (restriction of the use of certain hazardous substances in electrical and electronic equipment)**

including their amendments up to the date mentioned below.

The following harmonized standards were applied:

• EN 61010-1:2020

Safety requirements for electrical equipment for measurement, control and laboratory use -
Part 1: General requirements

• EN 61326-1:2013

Electrical equipment for measurement, control and laboratory use -
EMC requirements -
Part 1: General requirements

• EN 61000-3-2:2019

Electromagnetic compatibility (EMC)
Part 3-2: Limits - Limits for harmonic current emissions

• EN 61000-3-3:2020

Electromagnetic compatibility (EMC)
Part 3: Limits -
Section 3: Limitation of voltage fluctuations and flicker in low-voltage
supply systems for equipment with rated current ≤ 16 A
IEC 62366-1:2021
Suitability for use

Digitally signed by Bolea Petru
Date: 2023.07.13 08:57:34 EEST
Reason: MoldSign Signature
Location: Moldova

In addition, the following in-house standards were applied: **ISO 9001:2015; ISO 13485:2016**

Nieder-Olm, 23.11.2022

Stefan Schock
Managing Director

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