

SAO Y BẢN CHÍNH
Ngày.....tháng.....năm.....



Declaration of Conformity

We,

Colenta Labortechnik GmbH & Co KG
Neunkirchner Strasse 117
A – 2700 Wiener Neustadt,

declare under our sole responsibility that the product

MEDIPHOT Protective Apparel

(Medical Device Class I):

Coat Apron

Double Sided Coat Apron

Dental Apron

Panoramic Apron

Thyroid Shield

Skirt and Vest

Mini Aprons

Protective Gloves

X-Ray Goggles

Gonad Shield

Ovarian Shield

to which this declaration relates is in conformity with

MDD 93/42/EEC of June 14th, 1993 and MDD 07/47 EEC of September 5th, 2007

and are in conformity with the national standard transponding harmonized standard IEC 61331-1:2014 and IEC 61331-3:2014.

A quality management System based on the ISO 13485:2012+AC:2012 has been certified by mdc medical device certification GmbH (valid until 14.03.2020) and ISO 9001:2008 has been certified by DNV GL Business Assurance Zertifizierung und Umweltgutachter GmbH (valid until 15.09.2018)

Wiener Neustadt, September 20th, 2017



GIÁM ĐỐC

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GmbH & Co. KG

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