

CERTIFICATE

Number: 2078519

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Unitron Group B.V.

Schansestraat 7
4515 RN IJzendijke
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

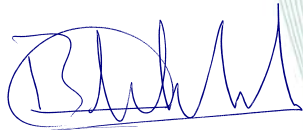
Design and development of active medical mechatronic devices, including electronics, mechanics and software, for the area of anaesthesiology, cardiovascular, dentistry, dermatology, neurology, cancer clinics and respiratory.

Manufacturing, distribution and service of active medical mechatronic devices, including electronics and mechanics

Certificate expiry date: 1 December 2022
Certificate effective date: 28 March 2022
Certified since: 1 January 2005

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

To certificate: 2078519

The management system of the organization(s) and/or location(s) of:

Unitron Group B.V.

Schansestraat 7
4515 RN IJzendijke
The Netherlands

Certified organization(s) and/or locations:

Different scope

Unitron Group B.V.
Schansestraat 9
4515 RN IJzendijke
The Netherlands

Design and development of active medical mechatronic devices, including electronics, mechanics and software, for the area of anaesthesiology, cardiovascular, dentistry, dermatology, neurology, cancer clinics and respiratory.
Manufacturing, distribution and service of active medical mechatronic devices, including electronics and mechanics

Unitron InnoTech B.V.
Asveldweg 2
7556 BP Hengelo
The Netherlands

Design and development of active medical mechatronic devices, including electronics, mechanics and software, for the area of anaesthesiology, cardiovascular, dentistry, dermatology, neurology, cancer clinics and respiratory.

Addendum expiry date: 1 December 2022

Addendum effective date: 28 March 2022