

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, development, manufacture, distribution and service of active medical devices for the area of anaesthesiology, cardiovascular, dentistry, dermatology, cancer clinics.

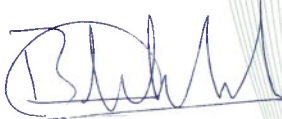
Certificate expiry date: 1 December 2019

Certificate effective date: 1 March 2019

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

© Integral publication of this certificate and adjoining reports is allowed



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

Design, development and manufacture of active medical devices for the area of anaesthesiology, cardiovascular, dentistry, dermatology, cancer clinics

Addendum expiry date: 1 December 2019

Addendum effective date: 1 March 2019