

# 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 2028  
Certificate effective date: 1 December 2025  
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.M. McKenzie  
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 IJzendinge  
The Netherlands

Certified organization(s) and/or locations:

Different scope

Unitron Group B.V.  
Schansestraat 9  
4515 RN IJzendinge  
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  
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 2028

Addendum effective date: 1 January 2005