Certificate BE14/223575447



The management system of

Optimized Radiochemical Applications sprl (ORA)

Rue de la Salette 15 5600 Neuville, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, development, manufacture and distribution of NEPTIS® system: synthesizer for the automated production of [18F] fluoride-based radiotracers.

This certificate is valid from 23 March 2020 until 22 March 2023 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 28 April 2014.

Re certification audit due before 17 October 2022.

Authorised by

Pieter Weterings Certification Manager

SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

SGS Belgium 13485-2 0308

Page 1 of 1





Accreditation Number

005-QMS EN ISO/IEC 17021-1:2015



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.