

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

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Accreditation Number

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