



Certificate BE14/223575447

The management system of

Optimized Radiochemical Applications sprl (ORA)

Rue de la Gendarmerie 50B
5600 Philippeville, 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.

Additional facilities

Rue de la Salette 15, 5600 Neuville, Belgium

This certificate is valid from 01/06/2018 until 27/04/2020 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 28/04/2014.

Re certification audit due before 27/03/2020.

Authorised by

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Certification Manager

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Page 1 of 1



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