

Certificate BE23/00000089

The management system of

Optimized Radiochemical Applications srl (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

Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

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

This certificate is valid from 27 January 2026 until 21 March 2029 and remains valid subject to satisfactory surveillance audits.

Issue 4. Organization certified since 28 April 2014 and first certified by SGS under UKAS since 01 April 2023.

L. Moran

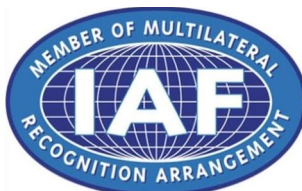
Authorised by

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