

Certificate BE23/00000089

SGS

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**

For the following activities

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

This certificate is valid from 01 April 2023 until 22 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 1. Organization certified since 28 April 2014 and first certified by SGS under UKAS since 01 April 2023.

Last certificate expiry date 22 March 2023. Recertification audit date 24 November 2022.

*Jonathan M. Hall*

Authorised by  
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