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DECLARATION OF CONFORMITY

We, Pixmeo SARL, 266 rue de Bernex, CH-1233 Bernex, Switzerland, declare under our full responsibility that the following medical device:

"**OsiriX MD**"

is produced under our supervision and responsibility. This product is for visualisation and manipulation of digital medical images for diagnostic imaging in medicine. This product is in conformity with the applicable provisions of: Council Directive 93/42/EEC concerning medical devices.

Classification according to Annex IX (MDD 93/42/EEC):

Class IIa, based on technical file no: DT1301214

Certificate of conformance (ID 170770516) has been delivered on 07.10.2020 (and valid until 26.05.2024) according to annex II of the Medical Device Directive 93/42/CEE and on the certificate ISO 13485 n°1000130446 has been delivered on 07.10.2023 (and valid until 06.10.2026) by the following organism : **DQS Medizinprodukte GmbH,** August-Schanz-Str. 21, 60433 Frankfurt am Main, Germany (no 0297).

An agreement has been signed with **DQS Medizinprodukte GmbH** for the continuation of MDD surveillance activities and extension of the existing certification during the MDD to MDR transition period. The maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607) is: 31.12.2028.

GMDN code of the product is 40943.

Validity date for this document is until 31.12.2028.

Place and date of issue: Bernex, 09.01.2025

Antoine Rosset

Antoine Rosset, Director