

DECLARATION OF CONFORMITY

Name and address of legal manufacturer:

LOG10 B.V.
Quinten Matsyslaan 85
5642 JC Eindhoven
The Netherlands
SRN: NL-MF-000000057

Declaration:

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Description: Integrated washer, disinfectant & sterilizer for Dental instruments
Model(s): Summox One System
Type Number: 50101
Basic UDI: 8720299274750101PA
Intended Purpose: The Summox One System is intended to wash, disinfect, lubricate, and sterilize reusable dental instruments that are carried in a Summox Smart Container. Furthermore, the Summox One System is intended to close and seal Summox Smart Containers, which allows storage of the dental instruments: in a sterile manner where applicable.


Classified as **Class IIb** medical device, it meets all the provisions of the Regulation (EU) 2017/745. Covered by the "CE Marking of Conformity Certificate", reference number: **<00000> issued on <DATE DD/MM/YYYY>**.

The manufacturer and product are certified by the notified body listed below:

Name and address of Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam Netherlands Notified Body number : 2797
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The Technical Documentation is available in the form of product file at the business premises of LOG10 B.V.

Date of issue: 24 FEB 2025

Signature:	
<i>Signed for and on behalf of LOG10 B.V.</i>	
Name:	Menco Verduin
Function:	Managing Director LOG10 B.V.
Place of issue:	Eindhoven, The Netherlands