

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 decontaminate reusable dental instruments that are carried in a Summox Smart Container. All types of instruments are cleaned, disinfected, dried, and cooled; non-hollow instruments may additionally be sterilized, and dental handpieces may be lubricated. 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: MDR 825975.

Conformity assessment was carried out in accordance with Annex IX of the Regulation (EU) 2017/745.

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: DD MMM YYYY

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