

EU DECLARATION OF CONFORMITY

Company Name: AQUA MEDİKAL TIBBİ ARAG VE GEREG İNS. SAN. DİŞ Tic. LTD.ŞTi.
Address: Esentepe Mh. 2953 Sk. No:54/A SULTANGAZI İSTANBUL TURKEY

We declare that we are the manufacturer of the devices listed below and that the devices comply with the Medical Device Regulation (EU) 2017/745 (MDR) and meet all relevant requirements within the MDR.

Product Name:

POVIDONE IODINE 10% SOLUTION

Basic UDI-DI: 868052562POVIDONELX

Type	Reference No.	UDI-DI
1000 ML	AQ 42	8680525621038
100 ML spray	AQ 38	8680525622905
30 ML spray	AQ 33	8680525621021

The products are in Class I according to section 4.1, rule 1 in Annex VIII of the Medical Device Regulation.

Conformity Assessment Path: Annex-IV Declaration of Conformity (Annex II & Annex III)

This Declaration of Conformity has been created under the sole responsibility of the manufacturer.

Publication date: 11.08.2021.



Name: MEHMET TOKUR
Position: GENERAL MANAGER
Signature:

AQUA MEDİKAL TIBBİ ARAG VE GEREGLER
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No: 54/A Sultangazi / İSTANBUL
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