

EC DECLARATION OF CONFORMITY

Company Name

: AQUA MEDİKAL TIBBİ ARAÇ VE GEREÇ İNŞ. SAN. DIŞ TİC. LTD.ŞTİ.

Address

: Esentepe Mh. 2953 Sk. No:54/A SULTANGAZİ 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.

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

The products are in Class I according to rule 1, 5 in Annex VIII of the Medical Device Regulation.

This Declaration of Conformity has been created under the sole responsibility of the manufacturer. The products are in Class I according to rule 1, 5 in Annex VIII of the Medical Device Regulation.

Applied Harmonized Standards, National Standard or other Normative Documents

Product Name and Type : ALCOHOL SWAB

Publication Date

: 11.08.2021

SIGN

GENERAL MANAGER

MEHMET TOKUR

AQUA MEDIMAL TIBBI ARAÇ VE GENEÇ NŞAAT SANAVÎ DIŞ TİÇARET LIMIZED ŞIR SERREÇE MANALESI 296 ŞIR 1 ELOK NO.54 SILMIŞBƏZ I ISTAN 12 476 SIŞ SIKÇIYKOV V.D.07.02.60