



EU DECLARATION OF CONFORMITY

AQUA MEDİKAL TIBBİ ARAÇ VE GEREÇLER İNŞAAT SAN. DIŞ. TİC. LTD. ŞTİ

ADDRESS : ESENTEPE MAH. 2953 SOK.11 BLOK No:54 SULTANGAZI / İSTANBUL, Türkiye
WAREHOUSE ADDRESS : ESENTEPE MAH. 2953 SOK.11 BLOK No:54 SULTANGAZI / İSTANBUL, Türkiye

Phone : 0 (212) 476 51 53
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E-mail : iletisim@aquamedikal.com

EU declaration of conformity according to Annex II of Directive 93/42/EEC

We declare that the products mentioned above comply with the requirements of Directive 2007/47/EC including Directive 93/42/EEC on medical devices. All relevant supporting documents are available at the manufacturer's facility.

Product : Aquatouch Lice Spray
Class : MDD 93/42/EEC, Annex IX, Class IIa, Rule 4
Conformity Assessment Procedure : MDD 93/42/EEC Annex II, excluding Article 4
GMDN Code : 45370
Brand : Aquatouch
Intended Use : Effective in the elimination of head lice, pubic lice, and body lice.

AQUA MEDİKAL declares that the products described above comply with the relevant provisions of Directive 93/42/EEC dated June 14, 1993, and subsequent revisions and amendments.

AQUA MEDİKAL implements and maintains a documented post-market experience monitoring process, including reporting of reportable incidents to Competent Authorities, as outlined in the European Medical Device Vigilance System Guidance.

AQUA MEDİKAL declares its commitment to fulfill the obligations of the approved quality system, maintain approved quality, and ensure the adequacy and effectiveness of the approved quality system.

The products have been evaluated for conformity by an approved Notified Body and a CE certificate has been issued.

Refer to Annex 1 Applicable Standards List for product standards.



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Approved Organization Name : UDEM. UDEM International Certification. Auditing
Training Centre Industry and Trade Inc. Co.
Approved Organization Number : 2292
CE Certificate Number : M.2021.106.14611
CE Certificate Publication Date : 21.05.2021
CE Certificate Expiration Date : 31.12.2028

General Manager: Mehmet Tokur

List of products:

Reference Code	Name of the product	Size
BIT-50	Lice Spray	50 ml
BIT-100	Lice Spray	100 ml
BIT-200	Lice Spray	200 ml
BIT-1000	Lice Spray	1000 ml