EC Declaration of Conformity

Manufacturer:
Name：Acro Biotech, Inc.
Address：4650 Arrow Highway, Suite D-6 Montclair, CA 91763, U.S.A

European Representative:
Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster , Germany

Product Name: Urinalysis Reagent Strips
(CA/ASC/BLO/BIL/URO/KET/GLU/PRO/NIT/LEU/PH/SG/ALB/CRE)
Model: Dipstick
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 11 70 02 02 00

We, Acro Biotech, Inc., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Montclair on 25/05/2022

Signature:
Name: Joseph Fan
Position: President

ACRO BIOTECH, INC

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