



EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III

Manufacturer: ACRO BIOTECH LLC 9500 7th Street Unit M Rancho Cucamonga,
CA 91730

Product: HIV 1.2 Rapid Test Cassette

Product code: IHI-402

Classification: Other device (all devices except Annex II and self-testing devices)

European Representative:

Name: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

We herewith declare on our sole responsibility that all batches of the above mentioned product are conform with the Essential Requirements of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

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—2019, 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 24/05/2022

Dr. Mathias Volk
Chemist, Safety officer

ACRO BIOTECH, INC