

EC DECLARATION OF CONFORMITY

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

Manufacturer: Biosynex Deutschland GmbH

Robert-Bosch-Breite 23, 37079 Goettingen, Germany

Product: Ethylalcohol dipstick, cut-off 0.1 pro mil / 10mg/dl, saliva

Product code: C-ALC-1S

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

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.

This EC declaration of conformity was prepared in responsibility of the manufacturer and the below mentioned safety officer.

Goettingen, 2013-01-04 Biosynex Deutschland GmbH

ppa. Dr. Gerd Hagendorff Safety officer

This document is valid until 2014-12-31.

