SAO Y BẢN CHÍNH
Ngày 10 tháng 9 năm 2021

RECIPE

EC-DECLARATION OF CONFORMITY

We hereby declare that the below mentioned devices comply with the directive on in vitro diagnostic medical devices 98/79/EC. In our capacity as manufacturer we carry the exclusive responsibility for the issuing of the declaration of conformity.

Name and Address of the Manufacturer:

RECIPE Chemicals + Instruments GmbH, Dessauerstraße 3, 80995 München, Germany
Phone: +49/89/54 70 81 – 0, Fax: -11, info@recipe.de, www.recipe.de

CÔNG TY CỔ PHẦN THIẾT BỊ VÀ HÓA CHẤT THĂNG LONG

GIÁM ĐỐC ĐIỀU HÀNH
Nguyễn Hải Hà

In Vitro Medical Device(s):

Product Identificator	EDMA Code	Product Name
Order No.: MS10000	11.90.01.90	ClinSpot® LC-MS/MS Complete Kit for Amino Acids and Acylcarnitines in Dried Blood Spots (DBS)
Order No.: MS10100	11.90.01.90	ClinSpot® LC-MS/MS Complete Kit for Amino Acids and Acylcarnitines in Dried Blood Spots (DBS) with Filter-Plates
		Components and Accessories:
Order No.: MS10005	11.90.01.01	Autosampler Washing Solution
Order No.: MS10010	11.90.01.01	Mobile Phase
Order No.: MS10012 MS10012A	11.50.03.03	Internal Standard
Order No.: MS10014	11.90.01.01	Optimisation Mix
Order No.: MS10021	11.90.01.01	Reagent A
Order No.: MS10022	11.90.01.01	Reagent B
Order No.: MS10023	11.90.01.01	Reagent C
Order No.: MS10040	21.05.10.02	96-Well-Plates (370 µl)
Order No.: MS10041	21.05.10.02	Covers for 96-Well-Plates
Order No.: MS10140	21.05.10.02	96-Well-Filter-Plates (500 µl) with covers
Order No.: MS10042	21.05.10.02	*Protective Sheets for 96-Well-Plates
Order No.: MS10045	21.05.10.02	*Backpressure regulator
Order No.: MS10046	21.05.10.02	*Replacement cartridge gold coat
Order No.: FK7400	21.05.10.02	*Inline-Filter
Order No.: FK7340	21.05.10.02	*Sealings and sieves for order no. FK7400
Order No.: MS10182	11.50.90.90	Dried Blood Spot Control, Level I, II

Classification:

Annex II, List B (directive 98/79/EC)
*other devices (directive 98/79/EC)

Conformity Assessment Procedure:

Annex IV (directive 98/79/EC)
*Annex III (directive 98/79/EC)

Certificate(s) and Notified Body:

Certificate DIN EN ISO 13485 (Certificate No. MD574425), EC Certificate No. CE635228 (Full Quality Assurance Certificate)
Notified Body: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 Amsterdam, The Netherlands (ID Nr. 2797).

Standards Applied:

Harmonised standards under the directive 98/79/EC, as applicable
CLSI Documents: NBS01-A6, NBS04-A, EP05-A2, EP06-A, EP09-A3, EP15-A2, EP17-A2, EP25-A

Date of Validity:

This declaration of conformity replaces the declaration of conformity dated from 28.06.2019 and is valid until 26.05.2024.

Authorised Signatory:

Date and Signature:

02.11.2020

Dr. Andreas Peruf,
Associate Manager Regulatory Affairs