Certificate Number FR19/819943739

The quality management system of

HORIBA ABX SAS

Parc Euromédecine Rue du Caducée BP 7290
34184 Montpellier Cedex 4 FRANCE

Dun & Bradstreet D-U-N-S identification number : 27-364-7420

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]
Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009
Canada:
Medical Devices Regulations – Part 1 SOR 98/282
Japan:
MHLW Ministerial Ordinance 169 / Article 4 to Article 68 / PMD Act
United States:
21 CFR 820 (OR 21 CFR 820.180 and 198) / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

Design, development, manufacture of in vitro diagnostic medical devices, i.c. reagents, controls, calibrators and analyzers, in the area of haematology, clinical chemistry, immunology, immune-haematology and coagulation, as well as installation and servicing activities

This certificate is valid from
Effective Date: 2019-05-03 until Expiry Date: 2022-05-02
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-10-24
Issue 1. Certified since 2019-05-03

Authorised by J Hall
Business Manager

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