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PARAMOUNT QUALITY CERTIFICATIONS

CERTIFICATE OF COMPLIANCE

This is to certify that the Products & spares of class I according to the Medical Devices Directive 93/42/EEC as Amended 2007/47/EC manufactured by:

NAME: METABOSCREEN CO., LTD.
ADDRESS: Nagata Bld. #301, Chuo 1-31-6, Nishi-ku, Yokohama City, Kanagawa, Postal Code: 220-0051, Japan
PRODUCTS: PathOC RightGene: High-Speed PCR Machine for Point of Care Testing (POCT), Test Kits for COVID-19 and Chemical Reagents for COVID-19 Testing

COMPLIES WITH THE REQUIREMENTS APPLICABLE TO IT

The Certification Body has performed an independent audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Medical Devices Directive 93/42/EEC as Amended 2007/47/EC.

THIS CERTIFICATE IS ISSUED UNDER THE FOLLOWING CONDITIONS:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown below can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certification Calendar:

Client Id: 1370

Certificate No: 2125/JAPAN-CE/081020

Registered on: 08.10.2020

Issued on: 08.10.2020

Expires on: 07.10.2023

1st Surveillance on/before: 07.10.2021

2nd Surveillance on/before: 07.10.2022



Authorized Signatory