

ISO 13485

Management System Certificate



Certificate Number : JQA-MD0010

Organization :

HORIBA, LTD.

2 MIYANOHIGASHI-CHO, KISSHOIN, MINAMI-KU, KYOTO-SHI, KYOTO, JAPAN



JQA certifies that the above organization operates the Quality Management System, within the scope of the Appendix attached, which has been assessed and found to comply with the requirements of,

ISO 13485:2003 / JIS Q 13485 :2005

Registration Date : March 10, 2006

Last Renewal Date : March 10, 2009

Expiry Date : March 9, 2012

A handwritten signature in black ink, appearing to read 'O. Morimoto'.

OSAMU MORIMOTO
PRESIDENT

JAPAN QUALITY ASSURANCE ORGANIZATION

To be used in conjunction with attached Appendix.

TOKYO, JAPAN



08.08 D7501029E

ISO 13485

Appendix



Certificate Number : JQA-MD0010

1 / 1

Organization :

HORIBA, LTD.

Scope of Registration:

- THE DESIGN / DEVELOPMENT, MANUFACTURE, SALES, INSTALLATION, FIELD SERVICING AND REPAIR OF FIELD RETURNS OF
BLOOD ANALYZER*¹
URINE AND FECAL ANALYZER*¹
 - THE DESIGN / DEVELOPMENT, MANUFACTURE AND SALES OF IN VITRO DIAGNOSTIC REAGENT*² FOR
BLOOD ANALYZER
URINE AND FECAL ANALYZER
- *¹EXCEPT SPECIALLY CONTROLLED MEDICAL DEVICES IN THE PHARMACEUTICAL AFFAIRS LAW
*²EXCEPT IN VITRO DIAGNOSTIC REAGENT WHICH CORRESPONDS TO CLASSIII IN THE PHARMACEUTICAL AFFAIRS LAW

ASSOCIATED ORGANIZATION:

- TOKYO SALES OFFICE
ARUTE BUILDING HIGASHIKANDA, 1-7-8 HIGASHIKANDA, CHIYODA-KU, TOKYO, JAPAN
- NAGOYA SALES OFFICE
SUMITOMO SEIMEI CHIKUSA DAINI BUILDING, 3-15-31 AOI, HIGASHI-KU, NAGOYA-SHI, AICHI, JAPAN
- OSAKA SALES OFFICE
SHINOSAKA UENOTOYO BUILDING, 7-4-17 NISHINAKAJIMA, YODOGAWA-KU, OSAKA-SHI, OSAKA, JAPAN
- KYUSHU SALES OFFICE
YASUKAWA SANGYO BUILDING, 2-6-26 HAKATAEKIHIGASHI, HAKATA-KU, FUKUOKA-SHI, FUKUOKA, JAPAN
[THE SALES OF
BLOOD ANALYZER
URINE AND FECAL ANALYZER]

Registration Date : March 10, 2006

Last Renewal Date : March 10, 2009

Expiry Date : March 9, 2012

A handwritten signature in black ink, appearing to read 'Osamu Morimoto', written over a horizontal line.

OSAMU MORIMOTO
PRESIDENT

JAPAN QUALITY ASSURANCE ORGANIZATION

This Appendix is an integral part of the Certificate and should only be used in conjunction with the Certificate.

The JQA logo, consisting of the letters 'JQA' in a bold, blue, sans-serif font.