



Mast Group Ltd.  
 Mast House  
 Derby Road  
 Bootle  
 Merseyside L20 1EA  
 United Kingdom  
 Tel. +44 (0)151 933 7277  
 Fax +44 (0)151 944 1332  
 www.mastgrp.com

## EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various (M-----)	<b>MAST ASSURE™ Shigella Antisera</b> – for serological identification and epidemiological typing with polyvalent and monovalent (flagellar) antisera typing and grouping Shigella species.	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003)

Standards applied: EN ISO 13485:2012, ISO 9001:2008, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2012, EN ISO 15223-2:2010.

Declaration made by ..... Date: 4 January 2017

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 31 December 2020

Registered in England 632512  
 Mast House, Derby Road, Bootle, Merseyside, L20 1EA, United Kingdom





Mast Group Ltd.  
 Mast House  
 Derby Road  
 Bootle  
 Merseyside L20 1EA  
 United Kingdom  
 Tel. +44 (0)151 933 7277  
 Fax +44 (0)151 944 1332  
 www.mastgrp.com

## EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various (M-----)	<b>MAST ASSURE™ Salmonella Antisera</b> – for serological identification and epidemiological typing with polyvalent and monovalent O (somatic) and H (flagellar) typing antisera.	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003)

Standards applied: EN ISO 13485:2012, ISO 9001:2008, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2012, EN ISO 15223-2:2010.

Declaration made by ..... Date: 4 January 2017

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 31 December 2020



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Holds Certificate Number:

FM 724380

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**Design, manufacture and supply of in-vitro diagnostic devices and associated services.**

**The expiration date of this certificate is extended for 6 months in accordance with BSI Procedure GP 158 Business Continuity - Managing Extraordinary Events (Reference to IAF ID3)**

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-05-21

Effective Date: 2020-09-16

Expiry Date: 2021-11-30

Page: 1 of 2



...making excellence a habit.™



This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: FM 724380

Location

Registered Activities

Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Design, manufacture and supply of in-vitro diagnostic devices and associated services.

Mast Group Ltd  
Atlantic House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Manufacturing, QC and warehousing of IVD kits and reagents, bacteriological media and other kits and reagents for the life sciences industry.



Original Registration Date: 1994-06-14

Latest Revision Date: 2021-05-21

Effective Date: 2020-09-16

Expiry Date: 2021-11-30

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/CilentDirectory](http://www.bsigroup.com/CilentDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

# bsi.



By Royal Charter

## Certificate of Registration

### QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

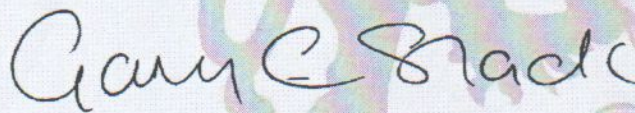
Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Holds Certificate Number:

**MD 724379**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07  
Latest Revision Date: 2021-05-28

Effective Date: 2021-06-01  
Expiry Date: 2021-11-30

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No:

**MD 724379**

Location

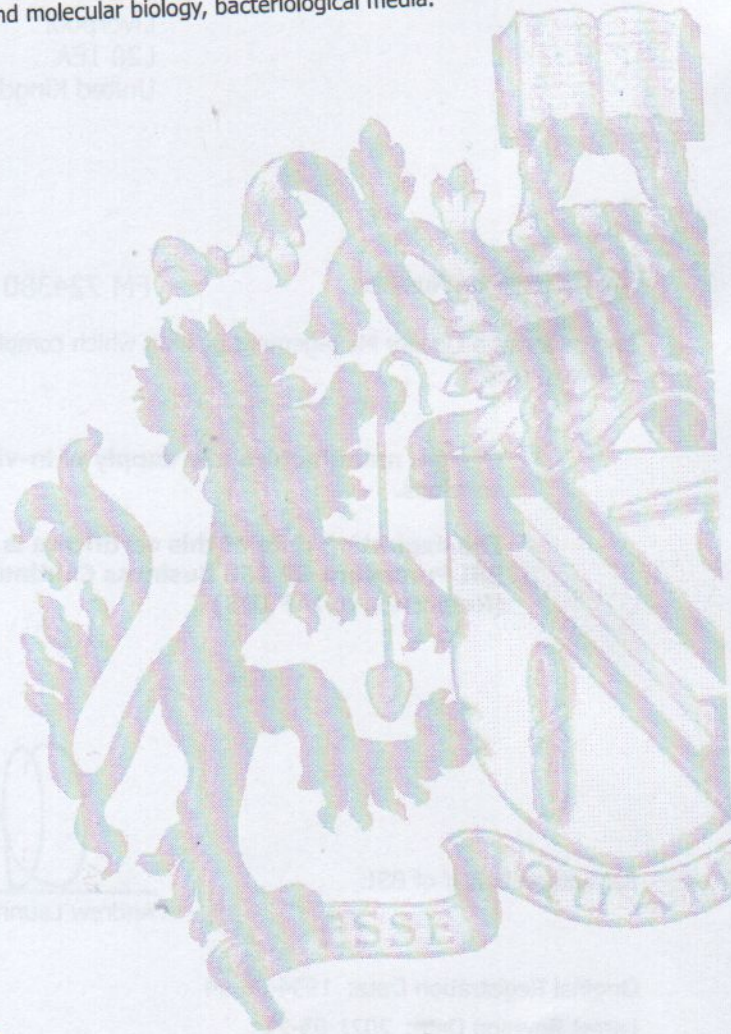
Registered Activities

Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media

Mast Group Ltd  
Atlantic House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Manufacture of IVD kits and reagents for clinical microbiology and molecular biology, bacteriological media.



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-05-28



Effective Date: 2021-06-01

Expiry Date: 2021-11-30

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.