Biolife Italiana S.r.l

Viale Monza, 272
20128 Milano - Italy
Tel +39 02.25.209.1
Fax +39 02.25.76.428
info@biolifeitaliana.it
www.biolifeitaliana.it

Certified Quality System
ISO 13485:2016
Cert. n° D2001500012
ISO 9001:2015
Cert. n° D2001500013

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Microbiology Leader
since 1968

EC Declaration of Conformity

to In Vitro Diagnostic Medical Devices Directive 98/79/EC
according to Annex III of the IVDD

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Viale Monza 272, 20128 Milan

declares that diagnostic reagents listed on the attached Device Schedule, classified as IVD Medical Devices, conform to the relevant provisions of the EC Council Directive 98/79/EC and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.
Biolife Italiana Sri agrees to develop, implement and maintain a documented postproduction experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.
Biolife Italiana Sri confirms that no medicinal products/drugs are incorporated in any device covered by the Device Schedule

Biolife Italiana Sri
Dr Massimo Brunelli

BIOLIFE ITALIANA s.r.l.
20[illegible]
Cod. IVA 01149250159

Managing Director

Milan, May 10, 2017

CE_ DECLARATION_BL_05-2017-REV.8

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DEVICE SCHEDULE

REF N° **DEVICE COMMERCIAL NAME**

DEHYDRATED CULTURE MEDIA FOR MICROBIOLOGY
EDMA CLASS. 14 01 01 01 / 14 03 01 01

IALI-500G

4053501	CHROMOGENIC SALMONELLA AG.BASE-100G
4053502	CHROMOGENIC SALMONELLA AG.BASE-500G