

## RUO/GP



### CERTIFICATE OF COMPLIANCE

#### LLOYD'S REGISTER NEDERLAND B.V.

hereby declares that the certification assessment has demonstrated that

#### MALDI Biotyper®

MBT microflex LT/SH / MBT smart / MBT sirius one / MBT sirius Complete Solution for the confirmation of *Cronobacter* spp.

Manufactured and supplied by: Bruker Daltonik GmbH

news digest #004

# Food microbiology: some *sirius* news from MicroVal!

In February 2021, MicroVal has approved the modification and extension of Bruker's four certificates on food safety relevant species for the MALDI Biotyper<sup>®</sup> sirius and sirius one systems. The MALDI Biotyper<sup>®</sup> is a benchtop MALDI-TOF MS instrument enabling quick confirmation of suspected *Salmonella*, *Cronobacter*, *Campylobacter* and *Listeria* incl. *L. monocytogenes* positive findings.

The MALDI Biotyper<sup>®</sup> was validated by MicroVal in 2018 as a confirmation method using mass spectrometry, starting from colony material. MicroVal is the first validation organization to issue certificates for confirmation methods based on ISO 16140-6. These certificates focus on the validation of the confirmation procedure included in the standardized reference method. So far, the MALDI Biotyper<sup>®</sup> is the only ISO 16140-6 certified MALDI-TOF method by MicroVal.

The certificates issued in 2018 were based on the use of the microflex® LT/SH and MALDI Biotyper® smart systems. With Bruker's launch of the new

MALDI Biotyper<sup>®</sup> sirius systems, an extension of the certificates of MicroVal was necessary and has been requested. For this project, data was reanalyzed and compared between MALDI Biotyper<sup>®</sup> smart and MALDI Biotyper<sup>®</sup> sirius, according to the food workflow of Bruker, to determine if the acceptance criteria were met. In addition, our latest software version MBT Compass HT (version 5.1) was successfully tested and showed equivalency on results output with the earlier released software MBT Compass (version 4.1).



MALDI Biotyper® sirius one and sirius

#### Certificate numbers, relevant species and details on agars

Scope of the certificate
<i>Cronobacter</i> spp. confirmation from colonies isolated on ESIA, CCI and any non-selective nutrient agars
Salmonella spp. confirmation from colonies isolated on XLD, BGA, Chromogenics based on C8-esterase activity detection (RAPID'Salmonella, Brilliance <sup>™</sup> Salmonella, ASAP, CASE) and non-selective nutrient agars
Confirmation of <i>Campylobacter</i> spp. from colonies isolated on mCCDA, Campy Cefex Agar, chromogenic agars (CampyFood® Agar, RAPID' <i>Campylobacter</i> ) and non-selective agar
Confirmation of <i>Listeria</i> spp. and <i>Listeria monocytogenes</i> (using the MBT Subtyping Module) from colonies isolated on Ottaviani & Agosti Agar, Palcam, Oxford, Modified Oxford and RAPID' <i>L. Mono</i> , and any non-selective nutrient agars

The MicroVal certificates state that the MALDI Biotyper<sup>®</sup> has been validated according to the following reference methods:

- Reference method: ISO 22964 (2017) Microbiology of the food chain Horizontal method for the detection of *Cronobacter* spp.
- Reference method: ISO 6579-1 and ISO 6579-2 -Microbiology of food and animal feeding stuffs -Horizontal method for the detection, enumeration and serotyping of *Salmonella* spp. - Part I: Detection of *Salmonella* spp.; and - Part 2: Enumeration by a miniaturized most probable number technique.
- Reference method: ISO 10272-1 and ISO 10272-2 -Microbiology of the food chain - Horizontal method for detection and enumeration of *Campylobacter* spp.
   Part 1: Detection method; and - Part 2: Colony-count technique.

 Reference method: ISO 11290-1 and ISO 11290-2

 Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. - Part 1: Detection method; and - Part 2: Enumeration method.

The renewed and modified certificates cover now the MALDI Biotyper® systems based on microflex® LT/SH / MALDI Biotyper® smart / MALDI Biotyper® sirius one / MALDI Biotyper® sirius. All certificates can be retrieved form the MicroVal website, together with the supporting validation report (see Confirmation methods, view list): https://microval.org/en/issued-certificates/.

Visit our "<u>MALDI Biotyper</u><sup>®</sup> for Food Microbiology" webpage

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As of May 2021, Bruker Daltonik GmbH is now Bruker Daltonics GmbH & Co. KG.

Bruker Daltonics GmbH & Co. KG Bruker Scientific LLC

Bremen · Germany Phone +49 (0) 421-2205-0 Billerica, MA · USA Phone +1 (978) 663-3660

info.md@bruker.com - www.bruker.com/microbiology