CERTIFICATE OF COMPLIANCE

LRQA

hereby declares that the certification assessment has demonstrated that

foodproof® *Enterobacteriaceae* plus *Cronobacter* Detection Kits (Cat. No. R 310 15.1 or R 302 15.1), combined with reagent D (Cat. No. A500 02) and foodproof® StarPrep One Kit (Cat. No. S 400 07) or foodproof® Magnetic Preparation Kit IV (Cat. No. S 400 15) for DNA extraction

Manufactured and supplied by:
Hygiena Diagnostics GmbH
Hermannswerder 17
14473 Potsdam
Germany

has been validated and revealed to be at least equivalent to the reference method as demonstrated by the validation study report, which has been prepared by a MicroVal Expert Laboratory and approved by the MicroVal Technical Committee. The above-mentioned production facility complies to the QMS requirements as mentioned in the MicroVal Rules. The summary of the validation report is available on the MicroVal website: www.microval.org

Reference methods:

1. ISO 21528-1:2017 Microbiology of the food chain - Horizontal method for the detection and enumeration of *Enterobacteriaceae* - Part 1: Detection of *Enterobacteriaceae*
2. ISO 22964:2017 Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp.

Scope: Infant formula and infant cereals, Probiotics containing products, Ingredients, Environmental samples

The validation and certification has been performed in accordance with EN ISO 16140-2:2016, EN ISO 16140-2:2016/Amd. 1:2024 and the MicroVal Rules.

Certificate no.: 2007LR08091920

First approval date: 6 July 2010
Renewal date: 11 June 2026
Expiry date: 5 July 2030

ISSUED BY: LRQA Nederland B.V.
Rotterdam, The Netherlands

George Hintzenweg 77, 3068 AX Rotterdam, The Netherlands. Kvk nr.: 24247948
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA

The overview on the claims for the current LR08091920 certificate is given in the Table below:

Detection of *Enterobacteriacea* and/or detection of *Cronobacter* spp.

	Enrichment	Standard protocol: 100 g sample material* plus 900 ml BPW pre-warmed at 37 °C, 16 - 20 h at 37 °C ± 1 °C											
	Subcultivation	Standard protocol P1: 100 µl of BPW culture in 900 µl BPW, 3 - 4 h at 37 °C ±1 °C (shaking at 900 U/min)											
		Specific protocol P2: 100 µl of BPW culture in 900 µl BPW, 20 - 24 h at 37 °C ± 1 °C (shaking at 900 U/min)											
	Reagent D treatment	A 500 02											
	DNA extraction	Manual protocol **food**proof StarPrep One Kit						Automated protocol **food**proof MagPrep IV Kit					
		S 400 07						S 400 15					
	Real-time PCR	**food**proof EBC detection kit, Hybridization probes		**food**proof EBC detection kit, 5'Nuclease				**food**proof EBC detection kit, Hybridization probes		**food**proof EBC detection kit, 5'Nuclease			
		R 310 15.1		R 302 15.1				R 310 15.1		R 302 15.1			
	Thermocyclers	LC 480 II	LC 2.0	LC 480 II	IQ5	ABI 7500	Mx 3005	LC 480 II	LC 2.0	LC 480 II	IQ5	ABI 7500	Mx 3005
	Software version	1.5.1	4.1	1.5.1	2.0	2.0.6	MX4.1 d	1.5.1	4.1	1.5.1	2.0	2.0.6	MX4.1 d
Scope (including subcultivation Protocol)	Infant formula and infant cereals (P1)	X	X	X	X	X	X	X	X	X	X	X	X
	Probiotics containing products (P1)	X	X	X	X	X	X	X	X	X	X	X	X
	Probiotics containing products (P2)	X	X	X	X	X	X	X	X	X	X	X	X
	Ingredients (P1)	X	X	X	X	X	X	X	X	X	X	X	X
	Environmental samples (P1)	X	X	X	X	X	X	X	X	X	X	X	X

*specific sample preparations: see detection kit inserts

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Year modification	Description modification	Date approval MVTC
2026	Renewal of certificate, IFU INS-KIT230068-69-REVB, May 2026	11 June 2026 68th MVTC

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