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CONFIRMATION

Johner Institute

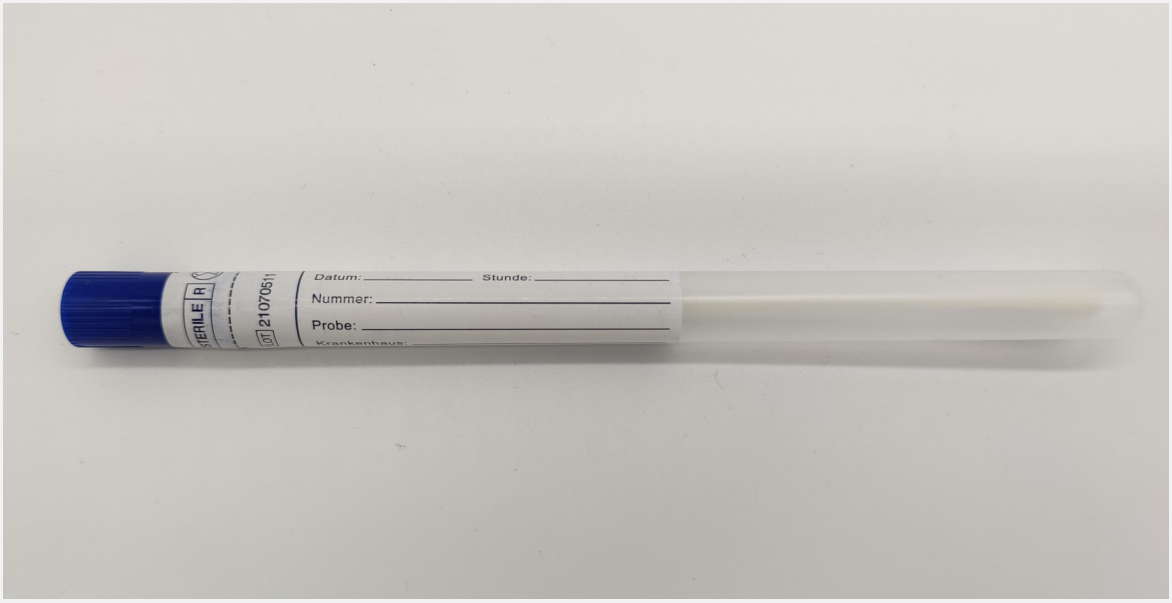
of Compliance

Johner Institute hereby confirms that the following product:

Product Specification	
Product	Disposable Sampling Swab, in transparent, dry transport tubes, sterile R, manufacturer: Babio Biotechnology Co., Ltd, China

of the company mentioned below:

Sponsor Information	
Sponsor	Synocura Healthcare GmbH, Hemmelrather Weg 201, 51377 Leverkusen



has been found conform to the current requirements of the listed standards and the recommendations therein (see reference report for detailed information): 32170-11-Report-Test-for-Sterility-Clean-Controlling

Standard Requirements	
EN ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process; 2020

Result: The test item (specification see above) was sterile.

Confirmation Details	
CONFIRMATION No.	32170-20
Reference Report	32170-21-Report-Test-for-Sterility-Clean-Controlling
Initial confirmation date	2021-11-12
Confirmation experiy date	2026-11-16

Dipl.-Ing (FH) Sarah Gruber
in-vitro Biocompatibility

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CONFIRMATION

Johner Institute

of Compliance

Johner Institute hereby confirms that the following product:

Product Specification	
Product	Disposable Sampling Swab, single packed, sterile R, manufacturer: Babio Biotechnology Co., Ltd, China

of the company mentioned below:

Sponsor Information	
Sponsor	Synocura Healthcare GmbH, Hemmelrather Weg 201, 51377 Leverkusen

has been found conform to the current requirements of the listed standards and the recommendations therein (see reference report for detailed information): 32170-11-Report-Test-for-Sterility-Clean-Controlling

Standard Requirements	
EN ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process; 2020

Result: The test item (specification see above) was sterile.

Confirmation Details	
CONFIRMATION No.	32170-10
Reference Report	32170-11-Report-Test-for-Sterility-Clean-Controlling
Initial confirmation date	2021-10-07
Confirmation experiy date	2026-10-11

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