

Declaration of Conformity

Manufacturer:	TAUNS Laboratories, Inc.
Address:	761-1, Kamishima, Izunokuni, Shizuoka 410-2325 Japan
SRN:	JP-MF-000007041
Authorised Representative:	Emergo Europe B.V.
Address:	Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SRN:	NL-AR-000000116
Product(s):	Capilia TB-Neo Extraction Buffer 20mL /Bottle
Basic UDI-DI	4987815TB02A3
Intended Use	This product is an extraction buffer using Capilia TB-Neo to prepare a sample that is employed for the identification test of <i>M.tuberculosis</i> when using a solid medium for acid-fast bacteria (AFB).
Classification (IVDR, Annex VIII):	Class A (Rule 5a)
Conformity Assessment Procedure:	Annex II, Annex III
Applied Common Specification:	N/A

We herewith declare that the above mentioned products meet the provisions of the Regulation (EU) 2017/746 for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Notified Body: N/A

EU Quality Management System Certificate: N/A

Place 761-1, Kamishima, Izunokuni,
Shizuoka 410-2325 Japan

Date 2022/4/4



Takayuki OHI
Management Representative