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):	CATB0871 Capilia TB-Neo 10T/BOX CATB0870 Capilia TB-Neo100T/BOX
Basic UDI-DI	4987815TB019Z
Intended Use	This device is intended to be used to assist the diagnosis of patients with tuberculosis, by qualitatively detecting mycobacterium antigens in a culture grown in a medium for acid-fast bacteria (AFB) inoculated with properly pre-treated clinical specimens, such as body fluid, tissue, and bronchoalveolar lavage fluid collected from patients with suspected tuberculosis. This device is not intended for use in self-testing or near patient testing, but is intended to be used by a physician or laboratory professional to make a diagnosis in a laboratory environment.
Classification (IVDR, Annex VIII):	Class C (Rule 3b)
Conformity Assessment Procedure:	Annex IX
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: TÜV SÜD Product Service GmbH
Notified Body number: 0123

EU Quality Management System Certificate: No. V12 107542 0002 Rev. 00

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

Date

February 1, 2022

T. Ohi

Takayuki OHI
Management Representative