ECHO ELECTRICITY CO., LTD.

SPIRIT

Declaration of Conformity

We

Name of manufacturer: Echo Electricity Co., Ltd.
Country of origin: Japan
Address: 1-2 Shinnatsunashi, Shirakawa-shi, Fukushima 961-0024 Japan
Telephone: +81-248-21-8261
Facsimile: +81-248-21-8852
European representative: Emergo Europe
Address: Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Declare under our sole responsibility the quality of

Product family name: Strip Meniscometry Tube
Product trade name: SMTube / Vita Test
Catalogue number: SMT11 / VTE50
UMDNS code: 17003 Tubes, Lacrimal
Classification: I

EU Classification (Rule: 5)	I		US FDA Classification	I	○
	I *	○		II	
	II a				
	II b			III	
	III				

Complies with all relevant requirement of:

☐ FDA Regulation
(Registration number: 886.1800 Establishment number: 3010811160
510(k) number: (exempt) PMA number: (exempt)

☐ Directive 93/42/EEC
(Annex: V)
Notified Body: SGS United Kingdom Ltd. CE0120
Address: 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

Applied standards:

Standard No	Title	Description
ISO13485:2003 ENISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes	Manufacturer of sterile lacrimal secretion function testing devices

Valid until: 6 October 2019

Signature and Date of issue: Shizuko Miyasaka 10 July 2017

Shizuko Miyasaka, Representative Director, Echo Electricity Co., Ltd.

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