Danmic Global, LLC

Declaration of Conformity (version 4)

PRODUCT IDENTIFICATION		
Product Name/b-UDI	Type/Model	Class
Tactile Sensory Evaluators/ b-UDI – 0850006095Aesthesio5R	Aesthesio®	Class I (Rule 1, 4.1 annex VIII)

MANUFACTURER		
Name of company	Address	SRN
Danmic Global, LLC	2059 Camden Avenue #281 San Jose, CA 95124 U.S.A.	US-MF-000021060

EUROPEAN AUTHORIZED REPRESENTATIVE		
Name of company	Address	
Code of Practice AB	Brunnsgatan 48 553 13 Jönköping Sweden	SE-AR-000003002

CONFORMITY ASSESSMENT	
Device Classification	Standards applied
Class I, Nonsterile, Non-measuring Device Rule 1	n/a for Class I device

Danmic Global declares that the above-mentioned product meets the provision of the EU Regulation MDR 2017/745 for medical devices

COMPANY REPRESENTATIVE: Jorgen M. Jensen

TITLE: President & CEO

SIGNATURE:

DATE: 03/08/2022