



Declaration of Conformity

We hereby declare that/it has been demonstrated that:

Product:

Product name: GSI Allegro
Intended purpose: Tympanometry Screener
Brand name: Grason-Stadler
Class.: Ila
Basic UDI-DI: 081004670_8508516_24

Manufactured by:

Name: Diagnostic Group, LLC dba SRN: US-MF-000026023
Grason-Stadler
Address: 10395 West 70th St Phone No.: +1 800.700.2282
Area code/Area: Eden Prairie, MN 55344
State/Country: USA

Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Conformity assessment: Annex IX (Quality system and technical documentation assessment)
MDR Certificate No.: G10 004862 0011
Valid until: 2028-07-04

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, D-80339 Munich / Germany
ID No.: 0123

This declaration is issued on the sole responsibility of:

Company: DGS Diagnostics A/S
Address: Audiometer Allé 1
Address: 5500 Middelfart
State/Country: Denmark

Place: Eden Prairie, MN

Signature: 
Name: Brandon Bell
Title: Director of Regulatory Affairs & Quality

Date: 2023-07-12
(YYYY-MM-DD)