



## Declaration of Conformity

We hereby declare that/it has been demonstrated that:

### Product:

Product name: GSI Pello  
Intended purpose: Clinical Audiometer  
Brand name: Grason-Stadler  
Class.: Ila  
Basic UDI-DI: 081004670 8107523 TR

### Manufactured by:

Name: **Diagnostic Group, LLC dba** SRN: **US-MF-000026023**  
**Grason-Stadler**  
Address: **10395 West 70<sup>th</sup> 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: 2023/08/08  
(YYYY-MM-DD)