Corporate Declaration of Conformity

According to Medical Device Directive (MDD) 93/42/EEC

Manufacturer	
	Auditdata A/S Dalbergstrøget 5-7 DH-2630 Taastrup Denmark
Conformity Assessment Procedure	
	Annex II.3 excluding (4) of the Medical Device Directive MDD 93/42/EEC
Registration	
	Danish Health and Medicines Authority Axel Heides Gade 1 2300 Copenhagen S, Denmark
Product Identification	
	Category: Hearing Medical Diagnostic
	Brand: Primus
	Model: **2000 Primus HIT Pro**
	Lot/Batches/Serial number: All issued serial numbers from 32000001
MDD Directive	
	Class I, Rules 12, MDD 93/42/EEC

The medical device compliance with the essential requirements in accordance with Annex I of the Medical Device Directive 93/42/EEC.

We declare under our sole responsibility that the products, to which this declaration relates, are in conformity with the Essential Requirements Annex I of the above directive.

Taastrup, August 2nd 2018

Dan Haugbøl, Corporate QA & Regulatory Manager

Doc ID: DN00969/02