


Auditdata

DECLARATION OF CONFORMITY

Manufacturer	Auditdata A/S Wildersgade 10B 1408 Copenhagen Denmark	
Conformity Assessment Procedure Registration	Annex II.3 excluding (4) of the Medical device Directive MDD 93/42/EEC Danish Health and Medicines Authority Axel Heides Gade 1 2300 Copenhagen S, Denmark	
Product Identification	MD Category: Brand: Type Model: SRN UDI/DI Lot/Batches/Serial number:	Hearing Medical Diagnostic (Hardware & Software) Primus 2000 PRIMUS HIT PRO - 05711781DHF2000ZC All issued serial numbers from 32000001
Risk classification	MDD 93/42/EEC Class I, Rule 12	

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. This DOC is valid until May 26th 2024 - EC certificate validity date.

Copenhagen, June 8th 2021

Dan Haugbøl, Director QA/RA & IT/CSO


Signature