Auditdata

DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT

Manufacturer name and address	Auditdata A/S Wildersgade 10B 1408 Copenhagen Denmark	
Notified Body name and address	Danish Health and Medicines Authority Axel Heides Gade 1 2300 Copenhagen S, Denmark	CE
Product Identification	MD Category:	Hearing Medical Diagnostic (Hardware)
	Trademark:	Primus HIT
	Type/Model:	2000 Primus HIT Pro (Unit), 2005 -1 HIT Unit
	CS (Common specification)	N/A no common specification has been published
	SRN:	DK-MF-000011415
	Basic UDI/DI:	05711781DHF2000ZC
	Risk class:	I, rule 13
	Lot/Batches/Serial number:	All issued serial numbers from 32000001
Intended purpose	The HIT Unit is intendent to apply sound to the hearing aid in a closed test box and obtain the acoustical output of the hearing aid in a coupler cavity equipped with a microphone. The HIT Unit is intended to be used together with the Software to provide objective indication of the characteristics of a Hearing Aid. Visualization of the obtained coupler microphone signal is only available in the Software application. The HIT Unit is indicated for technical quality inspection or fitting of hearing instruments with no clients involved.	
Conformity assessment	Annex I, II and III	

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Copenhagen, May 26th 2024

Denys Lebedev, QA/RA Manager