Statement on clinical data for RUBY 2 BTE & PG10 BTE SP

The clinical data held by the manufacturer for the devices in question comprise clinical evaluation[1] (including systematic literature reviews, validation, and usability activities), and post market clinical follow-up (PMCF)[2] in accordance with EU MDR 2017/745 (as amended) and applicable international standards.

In addition to the clinical data, the devices have been thoroughly verified according to the applicable general and particular international standards for hearing aids ensuring the technical and clinical performance are compliant and state-of-the-art.

Sincerely,

Anja Ravn

Anja Ravn

Manager, Clinical Affairs

Digitally signed by Mojila Violetta
Date: 2023.12.08 13:07:28 EET
Reason: MoldSign Signature
Location: Moldova

[1] *"Clinical Evaluation – Demant Platform Velox & Velox S"* Doc. No. *0901c76e80a8caff*

[2] *PMCF investigation 02 (BTE SP) & PMCF investigation 03 (BTE) in "Post-market Clinical Follow-up Report" Doc. No. 0901c76e80a6cf91*

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