

**DANCERT****DANISH TECHNOLOGICAL
INSTITUTE**

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CVR no. DK-29512094

EU - TYPE EXAMINATION CERTIFICATE

According to Directive 2014/34/EU Annex III

DTI 21ATEX0164X, Rev 01

2 Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014

3 EU - Type Examination Certificate Number: DTI 21ATEX0164X, Rev 01

4 Product: Hearing aids with type variants as specified under item 15

5 Manufacturer: WSAUD A/S

6 Address: Nymøllevej 6, 3540 Lynge, Danmark

7 This product and any acceptable variation thereto is specified in the schedule to this certificate and the documents therein referred to.

8 Dancert Danish Technological Institute, Notified Body number 1073, in accordance with Article 17 of Directive 2014/34/EU of the European Parliament and of the Council, dated 26 February 2014, certifies that this product has been found to comply with the Essential Health and Safety Requirements relating to the design and construction of products intended for use in potentially explosive atmospheres given in Annex II to the Directive.

The examination and test results are recorded in confidential Report No. DTI 21ATEX0164, J245687

9 Compliance with the Essential Health and Safety Requirements has been assured by compliance with: EN 60079-0:2018 incl. AC:2020 and EN IEC 60079-11:2012

except in respect of those requirements listed at item 18 of the Schedule.

10 If the sign "X" is placed after the certificate number, it indicates that the product is subject to the Specific Conditions of Use specified in the schedule to this certificate.

11 This EU-Type Examination Certificate relates only to the technical design of the specified product in accordance to the Directive 2014/34/EU. Further requirements of the Directive apply to the manufacturing process and supply of this product. These are not covered by this certificate.

12 The marking of the product shall include the following:



I M2 Ex ia I Mb

II 2G Ex ia IIC T4 Gb

II 2D Ex ia IIC T110 °C Db

Valid as of: 16-04-2024

For Dancert

Lars Bennedsen
CEO

**13 Schedule****14 Certificate Number DTI 21ATEX0164X Rev 01****15 Description of Product**

The Hearing Aids with the type listed under Item 4, is designed for use behind the ear delivered with a "receiver". They are designed in Ex-protection principle "intrinsically safe".

The fixed mounted secondary battery is of the "coin cell" type with a nominal voltage: 3.8 V. It is a Li-Ion button cell with Battery Size Code Z23. It has a dimension of about H:5.3 x Diameter: 7.85 mm.

Type variants:**Brand Name "REXTON"**

BiCore R-Li T 80
BiCore R-Li T 60
BiCore R-Li T 40
BiCore R-Li T 30
BiCore R-Li T 20
BiCore R-Li T sDemo

The internal design model linked to the above listed types are: "D12_RIC_LI13_T_MI_BT_MS"
Type variant called "sDemo" covers a version that afterwards by hearing aid professionals can be programmed as one of the other types.

Brand Name "Hörluchs"

ICP RIC 16 G7
Internal R&D name: D12_RIC_LI13_T_MI_BT_MS

Specifications

Secondary Battery, Li-ion (rechargeable),
Nominal voltage 3.8 V,
Battery size code Z23

Ambient temperature area: T_{amb} : 0°C to +50°C

The hearing aid is designed as Intrinsically Safe "ia" for use in classified areas Zone 1 and Zone 2. Group I (mining) or gas group IIC or dust group IIIC, with temperature class T4 or T110°C for Group III.

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17 Specific Conditions of Use

- If external devices are connected to the Hearing Aid e.g., for service or programming purposes, this interconnection must be done in the non-hazardous area (safe area).
- Only Hearing Aid batteries of the Li-ion button cell type size Z23 must be mounted by the manufacturer. Other battery types may impair safety.
- The battery may only be replaced by Hearing Aid professionals.
- All charging of the battery must take place in a non-hazardous (safe area). Only the charger delivered with the hearing Aid must be used.
- Marking: The hearing aid is by nature too small to be applied with the complete Ex marking. Therefore, a so-called "ATEX Safety Card" is issued with each hearing aid. This "ATEX Safety Card" contains the complete ATEX label information regarding the belonging "EU-Type Examination Certificate". The hearing aid contains a unique serial number in the battery compartment which also links the specific hearing aid together with the corresponding ATEX Safety Card which always must be brought by the user.

18 Essential Health and Safety Requirements

In addition to the Essential Health and Safety Requirements (EHSRs) covered by the standards listed at item 9, the following are considered relevant to this product, and conformity is demonstrated in the report:

None.

19 Drawings and Documents

Drawing title	Drawing no/ revision
D00192088_v1	ATEX Assertion, RX D12_RIC_LI13_T_MI_BT_MS Intrinsically Safe Concept
DeviceMasterRecord	D21009252_v1
DataSheet HearingAid	D00231625_v1
3D-Assembly HearingAid	D10991500_v1
Coating MotherBoard	D21011025-1_v1
3D-Assembly MotherBoard	D21009252_v1
Layout MotherBoard	21000273_v1
Schematic MotherBoard	D00223002_V1



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Schematic CoreAmplifier D00214724_v1
SupplierSpec 3.28MHz-MI-Antenna D00221410_v2

DataSheet S-Receiver D00207992_v3
DataSheet M-Receiver D00207988_v3
DataSheet P-Receiver D00207990_v3
DataSheet HP-Receiver D10669815_v2