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Your signs, your message of

Our Sign
BS 4823/2022-R

Editor(in)
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Regensburg
06.12.2022

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Application Article 97(1) in conjunction with Article 94 of Regulation (EU) 2017/745 on medical devices

Dear Dr. Oswald,

certificate No 51260-16-03 in accordance with Directive 93/42/EEC, Annex II without Section (4) loses upon expiry of 17. December 2022 is valid for the following products:

- Senti (model number SIH100097, SID100419, SID100433)
- Sentiero (model number SOH100098, SOH100360, SOD100497)
- ALGO7i (model number 101049)
- QSCREEN (model number 101199)
- nanoTymp (model number TU100948)
- Ear Probe (Type: EP-TE, EP-DP, EP-LT, EP-VIP, EP-TY)
- Headphone, Insert Phone (Type: HP, IP)
- Bone Conductor (Type: BC)
- Ear Coupler Cable (Type: ECC, ATA (A7i))

Following a formal examination of the documents submitted by you, there is no unacceptable risk to the health or safety of patients, users or other persons or other aspects of public health protection in the context of the assessment pursuant to Article 94 of Regulation (EU) 2017/745 on medical devices (MDR) resulting from the expiry of the above certificate.

In accordance with Article 97(1) of the MDR, those products may therefore continue to be placed on the market until the end of the ongoing conformity assessment procedure referred to in Annex IX MDR, but at the latest until 1 September 2023.

The following conditions must be met:

- The Labour Inspectorate of the Government of the Upper Palatinate shall be informed immediately of all measures/activities leading to a delay in the conformity assessment procedure initiated.

- Audit reports, reports on the examination of the technical documentation and letters of defects of the notified body shall be forwarded to the Trade Inspectorate without delay to the Government of the Oberpfalz.
- Indications of relevant risks within the meaning of Article 94(a) of the MDR shall be communicated without delay to the Labour Inspectorate to the Government of the Oberpfalz.

Please note the following information:

- The responsibility for placing the affected products on the market remains unchanged and exclusively with the manufacturer.
- The Trade Inspectorate at the Government of the Upper Palatinate may take measures in accordance with §§ 77-79 MPDG at any time, regardless of the time limit granted to remedy the non-compliance (e.g. if the manufacturer does not provide the above documents or does not properly comply with its obligation to cooperate under Section 139(1) of the MPDG).
- A competent authority of a Member State concerned may consider it necessary to take specific measures on its own territory.



Dipl.-Ing.(FH) Els
Gewerberat



Bayerische
Gewerbeaufsicht