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Notified body 2854 | SKTC-180

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EC Certificate IVDD 20 056 0124

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex III section 6 (Devices for self-testing)

Certificate holder: Phoenix Health s.r.o.

Ing. Štefana Višňovského 211/6
969 01 Banská Štiavnica
Slovakia



Related audit report: -

Other facility(ies): -

The certificate was issued with respect to the following scope:

MidStream Pregnancy Rapid Test

This certificate is effective from 12 April 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance. Initial version of the certificate was effective from 12 April 2022.

Certification has been authorized by

Radovan Macaj
Head of Notified body

bqs.

Certified In Vitro diagnostic
medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier relating to the device in accordance with Annex III section 6 of the directive and found that the design of the device conforms to the requirements laid down by Annex III. Please see also notes overleaf if any.

