EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III Section 6

No. **CE 706535**

Issued To: **ExSeed Health ApS**
Prags Boulevard 80
Copenhagen
2300
Denmark

In respect of:

The design and manufacture of the ExSeed home kit male fertility self-test

on the basis of our examination of the design relating to the device under the requirements of Council Directive 98/79/EC, Annex III Section 6, the design of the device conforms to the requirements of 98/79/EC.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2019-12-04** Date: **2019-12-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 706535

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Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
IVD0405	ExSeed	EH-1001-01	ExSeed Home Kit is a self-test that enables consumers (main target group: men, in the reproductive age) to monitor and track the progression of the parameters (semen quality) over time. ExSeed Home Kit does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the counter, in vitro use only. For complete assessment of male reproductive health, the user should consult a physician. ExSeed Home Kit comprises a smartphone app, an analysis device, collection cups, sample slides, wipes and labelling and packaging of the product.	Self-test

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Certificate History

Date	Reference Number	Action
Current	9717547	First Issue

First Issued: **2019-12-04** Date: **2019-12-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 706535 - Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

Issued to: **ExSeed Health ApS**
Njalsgade 21G
2300 Copenhagen S
Denmark

Date: 23 November 2022

Changes Approved:

Date	Reference Number	Action
23 November 2022	3768848	Change of legal manufacturer address

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23 November 2022

ExSeed Health ApS
Njalsgade 21G
2300 Copenhagen S
Denmark

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 706535	98/79/EC Annex III Section 6	3768848	Change of legal manufacturer address

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices