

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**

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 706535

Issued To:

**ExSeed Health ApS
Prags Boulevard 80
Copenhagen
2300
Denmark**

Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
IVD0405	ExSeed	EH-1001-01	<p>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.</p> <p>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.</p> <p>ExSeed Home Kit comprises a smartphone app, an analysis device, collection cups, sample slides, wipes and labelling and packaging of the product.</p>	Self-test

First Issued: **2019-12-04**

Date: **2019-12-04**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 706535

Issued To:

**ExSeed Health ApS
Prags Boulevard 80
Copenhagen
2300
Denmark**

Certificate History

Date	Reference Number	Action
Current	9717547	First Issue



First Issued: **2019-12-04**

Date: **2019-12-04**

Expiry Date: **2024-05-26**

...making excellence a habit.™