ExSeed Health ApS

Prags Boulevard 80, 2300 Copenhagen, Denmark

Manufacturer's Declaration of Conformity

In Vitro Diagnostic Medical Device Directive 98/79/EC

This is a declaration made in accordance with the requirements of Annex III section 6 of the In Vitro Diagnostic Medical Device Directive 98/79/EC as the conformity assessment route is via the Design Examination for self-testing devices relating the following device

Legal Manufacturer	ExSeed Health ApS
Legal Manufacturer's Address	Prags Boulevard 80, 2300 Copenhagen, Denmark
IVD Device Name	ExSeed
Product Code	EH-1001-01
Classification	IVD Self-test (non-Annex II)
GMDN Code	36744 (Analyser, sperm/semen)
Design Certificate Number	CE 706535
Notified Body	BSI Group - The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Notified Body No	2797

I, the undersigned, hereby declare that the device specified above complies with the applicable essential requirements of Annex I of the In Vitro Diagnostic Medical Device Directive 98/79/EC, and fulfils the obligations imposed by Annex III section 6 (Design Examination).

Date Signed	2019-12-06
Emil Andersen *Chief Scientific Officer ExSeed Health*	

1. Revision history

Revision	Comment	Changed by	Date
1.0	First Revision - correction to the notified body address, revised wording for the conformity assessment route statement, revision to the final statement and updated the notified body number from NB0086 to 2797, incorporation of revision history to the document and file name in the footer	EA	2019-08-14
2.0	Second revision - correction to the route statement, changed business address and small typo.	EA	2019-09-16