

EC DECLARATION OF CONFORMITY

IVD MEDICAL DEVICES DIRECTIVE 98/79/EC

MANUFACTURER:

HALOTECH DNA SL

ADDRESS:

C/ Faraday, 7 1ª Plta
Campus Cantoblanco
28049 Madrid
Spain

DECLARES under their responsibility that the products covered by this declaration conform with the Essential Requirements of EC directive 98/79/EC and its annexes.

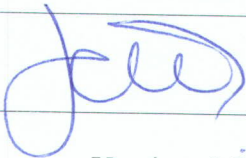
This declaration is supported by the Quality System certification based on the harmonized standard ISO 13485, with specific certificate number 9124.HDNA

HALOSPERM, DNA fragmentation assessment using SCD (*Sperm Chromatin Dispersion*) test.

HALOSPERM family include (**HALOSPERM®**, **HALOSPERM®G2**, **dynHALOSPERM®**)

(EDMS code: 1270059000)

DATE: July 22th, 2018

Name	Jaime Gosalvez Technical Manager
Signed	

Version, 2.2 (English version)