

EC Design-Examination Certificate

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

No. CE 610870
Issued To: **Church & Dwight Co., Inc.**
500 Charles Ewing Blvd.
Ewing
New Jersey
08628
USA

In respect of:

The Design and Manufacture of One Step Pregnancy and Ovulation Self-test Kits.

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2014-04-30**

Date: **2018-08-14**

Expiry Date: **2023-08-14**

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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.

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Product brands under this certification include:

Number	Part number	Product Name List
1	5010724 506370 (1 test/kit) 5010724 506387 (2 tests/kit) 5010724506387 (3 tests/kit)	First Response® Early Pregnancy Test
2	5010724 512074 (1 test/kit) 5010724 513392 (2 tests/kit)	Answer® One Minute, One Step Pregnancy Test
3	A909892972 (2 test/kit)	Confidelle Progress® Test Precoce Di Gravidanza
4	8002945770903 (1 test/kit)	Confidelle Progress® Test Precoce Di Gravidanza
5	8002945751803 (1 test/kit)	First Response® Test Precoce di Gravidanza
6	5010724525425	First Response TM Rapid Response Pregnancy Test (2 test/kit)
7	5000007397 – Belgium 5000007398 – Switzerland 5000007400 – Spain/Portugal 5000007401 – Finland/Sweden 5000007402 – France 5000007403 – Greece 5000007404 – Hungry	Predictor® Early Pregnancy Test

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	5000007406 – Netherlands 5000007407 – Turkey 5000012957 - Singapore 20502329 – 700ct (Bulk Count Test Sticks)	
8	5000020763-Belgium	Biover Medical 1 Pregnancy Self-Test
9	5000020762-Belgium	Life Test Pregnancy Self-Test
10	5000007420 – Belgium 5000007421 – Netherlands 5000007423 – Finland/Sweden 5000007424 – France 5000007425 – Greece 5000007427 – Intl 5000007430 – Intl (2 tests/kit) 5000007428 – Turkey 5000007431 – Netherlands (2 tests/kit) 5000012959 – Singapore 20502330 – 700ct (Bulk Count Test Sticks)	Predictor® Express Test – one minute test
11	5000007409 – Switzerland 5000007411 – Greece 5000014157 – Netherlands	Predictor® Early + Express Pregnancy Tests

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12	5000007432 - Belgium 5000007433 - Switzerland 5000007434 – France 5000007435 – Greece 5000007436 – Intl 5000007438 – Turkey 20502332 – 700ct (Bulk Count Test sticks)	Predictor® Ovulation Test
13	5000007396 – Austria/Germany	Femtest® Early Pregnancy Test
14	5000007488 – Austria/Germany	Femtest® Express Test – One Minute Test

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Certificate History

Date	Reference Number	Action
30 March 2014	8110086	Transfer from another Notified Body.
11 August 2014	8196027	Technical review of update to analog pregnancy test and addition of digitally read pregnancy test.
25 February 2015	8216729	Addition of Femtest®
25 May 2016	8486209	Removal of First Response® Easy Read Ovulation Test, and First Response® Daily Ovulation Test. Addition of Bluetooth, new product claim, new branding names.
26 September 2017	8775616	Removal of First response Pregnancy Pro Bluetooth smart Digital Pregnancy test. Addition of Biover Medical and Life Test pregnancy tests. Modification to pregnancy foil, and predictor test IFU and label changes.

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Date	Reference Number	Action
Current	8999491	<p>Certificate renewal. Removal of Femtest® Early Digital Pregnancy Test part number 5000007395, First Response™ Digital Pregnancy Test part number 010724529843, First Response™ Test & Confirm Dual Pregnancy Test (Analog & Digital) part number 5010724529850, Discover® Today One Minute, One Step Pregnancy Test (1 test) part number 5010724 510919 (1 test/kit) and Discover® Today One Minute, One Step Pregnancy Test (2 tests) part number 5010724 510926, Predictor Early Digital Pregnancy Test, Predictor Express Test – one-minute test: Switzerland part number 500007422, Finland/Sweden (2 tests) part number 500007429, Spain part number 500008487, Hungary part number 5000007426, Predictor Early + Express Pregnancy Tests France part number 500007408, Switzerland 500007409, Spain part number 500007410, Intl part number 500009078, First Response® Early Result Pregnancy Test (1 test/kit) 502780, Predictor Early Pregnancy 5000007405 Int. and 5000008486 Bel. (Duo), Predictor Ovulation test 5000007437 Netherlands.</p> <p>Addition of Added First Response® Early Pregnancy Test part number 5010724506387 (3 tests/kit), Answer® One Minute, One Step Pregnancy Test part number 5010724 513392 (2 tests/kit), Confidelle Progress® Test Precoce Di Gravidanza part number 8002945770903 (1 tests/kit), Predictor Early + Express Pregnancy Tests Netherlands part number 5000014157, new part number for Switzerland 500007409.</p>

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