



bloom

TSH EU Declaration of Conformity

4-4-6-7-2


25.05.2022, Version 1.2

Valid for the Technical Documentation Version: 2.X

The signatory, who represents the above-mentioned manufacturer, herewith declares under their sole responsibility that the product is in conformity with the relevant provisions of below-mentioned EC Directive(s).

Product Name	REF
Bloom Thyroid Test (TSH)	TSH-REF-1-1.X, TSH-REF-2-1.X

Manufacturer Name/Address	Authorized Representative Name/Address
Bloom Diagnostics AG Susenbergstraße 185 8044, Zürich, Switzerland	Bloom Diagnostics GmbH Börseplatz 6/2/19-20 1010 Vienna, Austria

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.		
Notified Body Name	Notified Body Address	Notified Body Number
BSI Group The Netherlands B.V.	Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands	 2797

The conformity is declared based on Annex IV, excluding Sections 4 and 6, of Directive 98/79/EC.

Issued EC Certificate number: CE 703283

The date when the CE marking was first affixed: 2021.10.29

Valid through : 2024-05-26

This declaration is valid for all products of the above design that are fabricated according to the respective fabrication documents.

Approved by:

25/05/2022 Signature ID: 557f132a7c...

25/05/2022 10:44:19 UTC

Angelica Kohlmann
(Executive Chairman)