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CRP EU Declaration of Conformity

4-4-3-7-1

25.05.2022, Version 1.0
Valid for the Technical Documentation Version: 1.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 Inflammation Test (CRP)	CRP-REF-3-1.X, CRP-REF-4-1.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
N/A	N/A	N/A

The conformity is declared based on Annex III of the Directive 98/79/EC.

The date when the CE marking was first affixed: 2022.05.25
Valid through : 2027-05-25

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

Approved by:

AK

SignNow e-signature ID: d551acffe2...
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Angelica Kohlmann
(Executive Chairman)