

Declaration of Conformity

Becton Dickinson and Company

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Conformity

-Directive 98/79/EC of the European Parliament and of the Council,
Annex III of Directive 98/79/EC

Assessment -Directive 2011/65/EU of the European Parliament and of the Council

Procedure: as amended by Delegated Directive (EU) 2015/863, Annex II

REF Product Name
441007 BD EpiCenter™

441007 BD EpiCenter™ System Software
440981 BD EpiCenter™ Multi User Module
440887 BD EpiCenter™ Plus Software

We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices. This declaration is issued under the sole responsibility of Becton, Dickinson and Company.

Date: July 19, 2021

Name and Authority:

Anne Zavertnik

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Vice President Regulatory Affairs, IDS

Signature:

Product:

Technical File Number: BALTER441007

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
Α	Initial Release