

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	PreAnalytiX GmbH Garstligweg 8 8634 Hombrechtikon Switzerland
Manufacturer SRN:	CH-MF-000033445
Authorised Representative:	QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, Germany
Authorised Representative SRN:	DE-AR-000004971
Product:	PAXgene® Blood RNA Tube SKU#: 762165
Basic UDI-DI:	4053727OQXSHDWXHN
Risk Class and Rule:	Class A (sterile) Annex VIII, Rule 5c
Intended Purpose:	<p>The PAXgene Blood RNA System consists of a blood collection tube (PAXgene Blood RNA Tube) and nucleic acid purification kit (PAXgene Blood RNA Kit). It is intended for the collection, storage, and transport of blood and stabilization of intracellular RNA in a closed tube and subsequent isolation and purification of host RNA from whole blood for RT-PCR used in molecular diagnostic testing.</p> <p>Performance characteristics for the PAXgene Blood RNA System have only been established with FOS and IL1B gene transcripts. The user is responsible for establishing appropriate PAXgene Blood RNA System performance characteristics for other target transcripts.</p>
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123
<p>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):</p>	

- Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices.

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input checked="" type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: V11 055425 0007 Rev. 02 EC Certificate Expiration Date: 2026-04-14
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX I & II+III	N/A

Common Specifications (CS): Common Specifications have not been issued for this product.

Authorised Signatory:	
Name & Title:	[Redacted]
Place of Issue:	[Redacted]
Date of Issue:	03-Mai-2023
Signature:	[Redacted]

Version:	Detailed Change Description:
01	Initial release.