HOLOGIC

Panther System
Declaration of Conformity

SIGNATURES ON FILE

Object of the Declaration:

Registered Name	Catalog No.	Basic UDI-DI
Panther System, Diagnostic	303095	**54200455DIAGPANTHER24**
Panther Fusion System	PRD-04172	
Panther Fusion Module	PRD-04173	
Procleix Panther System	303160	
Panther Upgrade Continuous Fluid and Waste + Waste to Drain + MTU Expansion	PRD-05845	
Panther System Continuous Fluid and Waste (Panther Plus)	PRD-06067	
Procleix Panther System (ART, Continuous Fluid and Waste)	PRD-06122	
Panther Link Base Configuration	PRD-06119	
Panther Link Connection	PRD-06120	
Panther Connect Track Ready Module	PRD-07161	
Panther Trax (Panther Workcell)*	PRD-05491	
Tomcat Instrument	ASY-07379	
SysCheck	301078	

*Commercialized as Bloodstream Track by Grifols

Technical File Reference: TFS-00010

Manufacturer's Name and Address: Hologic, Inc.
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Manufacturer's SRN: San Diego Facility: US-MF-000001646

Authorized Representative: Hologic BV
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Belgium

Authorized Representative SRN: BE-AR-000000127

Conformity Assessment Procedure: Self-Certified; Annex II and III

Classification/ Conformity Assessment: Class A *in vitro* diagnostic device per Rule 5, Annex VIII of EU 2017/746

EC Certificate No. /
EC Certificate Expiration Date: Not Applicable

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Date: 2025.10.07 08:24:35 EEST
Reason: MoldSign Signature
Location: Moldova
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Intended Purpose:

The Hologic Panther System consists of a variety of instrumentation specifically to be used for *in vitro* diagnostic procedures using various Hologic diagnostic/screening assays and other Hologic products.

1. Panther System (Diagnostic)

The Panther System is an integrated nucleic acid testing system which fully automates all steps necessary to perform Aptima™ assays from sample processing through amplification, detection, and data reduction.

2. Panther Fusion System

The Panther Fusion system is an integrated, fully automated in vitro diagnostic (IVD) clinical multiplex system. It is capable of performing nucleic acid-based tests from sample processing through amplification, detection, and data reduction.

The Panther Fusion system supports processing of assays that utilize nucleic acid detection technologies such as Polymerase Chain Reaction (PCR), Reverse Transcription PCR (RT-PCR), Real-Time PCR, Transcription Mediated Amplification (TMA), and Real-Time TMA or other similar technologies. Sample processing and nucleic acid capture steps as well as TMA assays are performed on the Panther System. The Panther System with the Panther Fusion Module is referred to as the Panther Fusion system, which can be used to perform PCR and RT-PCR assays.

3. Procleix Panther System (Blood Screening)

The Procleix Panther System is an integrated nucleic acid testing system which fully automates all steps necessary to perform Procleix assays from sample processing through amplification, detection, and data reduction. The Procleix assays are qualitative and/or quantitative, *in vitro* nucleic acid amplification tests for the detection of pathogenic viruses in human specimens, as defined in the assay package insert.

4. Panther Plus (Panther System, Continuous Fluid and Waste)

The Panther Plus optional upgrade has the same intended use as the base Panther System.

5. Panther Link

Information provided in the Dashboard Command reports is intended for use by laboratory professionals as a tool assessing (Panther) instrument operation and status.

6. Panther Trax (Panther Workcell)

For customers that have multiple Panther Systems, the Panther Trax system offers a configuration to physically link multiple Panther Systems via a track that transports specimens to designated Panther Systems for testing. Panther Plus and Panther Link configurations are required for the Panther Trax system. For additional information, refer to the appropriate *Panther Operator's Manual* and the *Panther Link Application Sheet.*

7. Tomcat Instrument

The Tomcat Instrument is an integrated sample handling instrument that fully automates the steps necessary to perform sample aliquoting from Input Container to Output Tube.

8. SysCheck

The SysCheck Reagent is used for performing a verification test of the Luminometer calibration factor. The use of the SysCheck Reagent effectively assesses the Luminometer.

Declaration of Conformity to Standards:

The devices covered by the present declaration are in conformity with the European Union (EU) in vitro Diagnostics Regulation (IVDR 2017/746), and, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This EC declaration of conformity is issued under the sole responsibility of Hologic, Inc.

Signed for and on behalf of Hologic, Inc.

Jill Wyland / Director, RA — Jill Wyland Digitally signed by Jill Wyland Date: 2024.06.21 07:58:18 -07'00' — San Diego, CA, US / 21Jun2024

Name / Title — Place / Date

Revision History:

Revision	Version/History Description	Issue Date	Regulatory Author
001	Initial Release	2022-05-11	Grace Alcaraz
002	Remove standards list as this is not a required Declaration of Conformity requirement. Updated footer to align with 04-03-16-SOP.	2024Mar07	Jill Wyland