

DECLARATION OF NON-IVD STATUS

We, *Grifols Diagnostic Solutions Inc.*, with business address at 4560 Horton Street, Emeryville, CA 94608, USA, hereby declare the disposables/ consumables used with the Procleix Ultrio Elite Assay and the Procleix Panther System are general laboratory use products and not considered as In-vitro Diagnostic devices (IVD) according to EU IVD Directive (98/79/EC), MEDDEV 2.14/1, and GHTF/SG1/N045:2008. These items include:

- Advanced Cleaning Solution – Part Number: 303085
- Multi-Tube Units (MTUs) – Part Number: 104772
- Waste Bag Kit – Part Number: 902731
- MTU Waste Cover – Part Number: 504405
- Reagent Spare Caps (TCR and Selection Reagents) – Part Number: CL0039
- Reagent Spare Caps (Amplification and Probe Reagents) – Part Number: CL0042
- Reagent Spare Caps (Enzyme, Discriminatory Probe Reagents) – Part Number: 501619
- Reagent Spare Caps (Target Enhancer Reagent) – Part Number: 903302
- Disposable Conductive Filter Tips (DiTis) – Part Number: 10612513

Article 1(2)(b) of the IVDD clearly states: “*Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination*”. All the above products are manufactured by third parties (i.e. the manufacturer) and not specifically intended by the manufacturers to be used for IVD examination. MEDDEV 2.14/1 gives examples of products used for general laboratory purpose and as IVD devices. All the IVD device examples given in MEDDEV 2.14/1 have certain special characteristics. Conversely, the consumables/ disposables used on the Procleix platform do not process these special characteristics that would make them IVD devices.

Section 9, Rule 5 of GHTF/SG1/N045 further states: “*any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are*

not deemed to be IVD medical devices". The disposables/ consumables listed above are indicated in the assay and instrument IFUs as necessary items and classified as Disposables/ Consumables/ Other. There is no separate IFU from the original manufacturers. Therefore, the products are not manufactured, sold or represented for use in any specific IVD application.

More importantly, the product's function relative to the Procleix blood screening platform does not make them IVD devices:

- **Advanced Cleaning Solution:** used for cleaning Panther Mag Wash Station during instrument maintenance. It is not part of a diagnostic process and has no effect on test results.
- **Multi-Tube Units (MTUs):** plastic tubes used as a reaction vessel. It is similar to a normal test tube and does not process special characteristics. It has minimum effect on test results.
- **Waste Bag Kit and MTU Waste Cover:** simply waste containers. Because specimens and assay reagents are deactivated before disposal, there is no safety concern. The two items have no effect on test results.
- **Spare Caps:** used to recap assay reagent vials after initial opening. Most assay reagents have a 30-day open kit shelf life when stored properly. That means the reagents can be reused if they are not used up the first time. Instead of using the original caps, each time a new spare cap is used to cap the reagent vials. They have minimum effect on test results.
- **Disposable Conductive Filter Tips (DiTis):** pipettes used by Panther to add specimens and reagents to MTU. They are simply general purpose pipettes and have minimum effect on test results.

We further declare there is no individual IFU for any of these disposables/ consumables and their usage is covered by assay Package Insert and instrument Operator's Manual. Pictures and labels of these products are provided in the next three (3) pages for clarification.

Advanced Cleaning Solution

Picture:

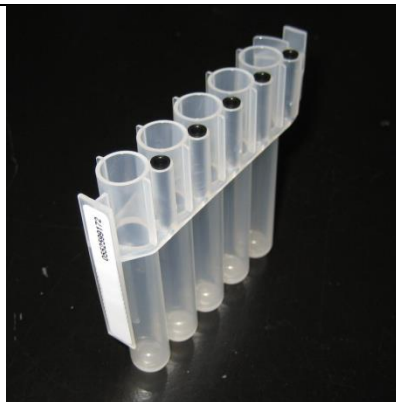


Label:

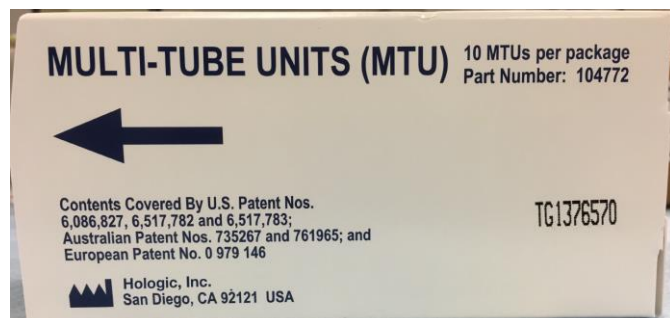


Multi-Tube Units

Picture:



Label:




Waste Bag Kit and MTU Waste Cover

<p>Picture:</p> 	<p>Label: <i>(no separate label for Waste Cover)</i></p> 
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<p>Reagent Spare Caps (TCR and Selection)</p> <p>Picture and Label:</p> 	<p>Reagent Spare Caps (Amplification and Probe)</p> <p>Picture and Label:</p> 
<p>Reagent Spare Caps (Enzyme, dProbe)</p> <p>Picture and Label:</p> 	<p>Reagent Spare Caps (Target Enhancer)</p> <p>Picture and Label:</p> 

Disposable Conductive Filter Tips (DiTis)

Picture:



Label:

REF	10 612 513	TECAN.
1000µl LiHa Disposable Tips with filter (conductive)		
Cont.	9600 pcs (10x960)	Transport conditions: -25°C / +35°C / 10% / 85%
	Purity factors and specifications are only guaranteed for one single use	 Products must be stored in a dry place, at room temperature and protected from direct solar radiation. 
LOT	A123456G	
	2019-08-28	10612513 A123456G
Tecan Trading AG, Seestraße 103, 8708 Männedorf, Switzerland Country of Origin: Germany		

Acknowledgement

GRIFOLS DIAGNOSTIC SOLUTIONS INC.



Signed by: _____
Name: PHILIPP NOVALES-LI, DMedSc, PhD, DPhil (Oxford)
Title: Director, Global Regulatory Affairs
Date: 05 January 2022

