

AUTHORIZATION

To: Medicines and Medical Devices Agency:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain) ("Grifols"), hereby authorize:

"GBG-MLD" SRL Address: Str. Albisoara 64/2, Chisinau MD -2005 (Moldova) ("**GBG-MLD**")

to promote, market, sell and service the following products, within the Republic of Moldova, in accordance with distribution agreement entered into between Grifols and GBG-MLD on 1 January 2022, as amended on 1 February 2022:

- Procleix Panther ART Instrument
- Procleix Xpress System including:
 - ✓ Procleix Xpress Pipettor
 - ✓ Procleix Xpress Software
- Bloodstream Software
- Reagent Equilibration System (RES)
- Procleix® Ultrio® Elite Assay including:
 - ✓ Procleix Ultrio Elite Assay
 - ✓ Procleix Ultrio Elite HIV, HCV, and HBV Discriminatory Probe Reagents
 - ✓ Procleix Ultrio Elite Target Enhancer Reagent
 - ✓ Procleix Ultrio Elite Negative Calibrators
 - ✓ Procleix Ultrio Elite Positive Calibrators
 - ✓ Procleix Ultrio Elite Assay Calibrator Kit
 - ✓ Procleix Oil Kit (Procleix and Procleix Tigris Systems)
 - ✓ Procleix Wash Solution Kit (Procleix and Procleix Tigris Systems)
 - ✓ Procleix Buffer for Deactivation Fluid Kit (Procleix and Procleix Tigris Systems)
 - ✓ Procleix Assay Fluids Kit (Procleix Panther System)
 - ✓ Procleix Auto Detect Reagents Kit (Procleix and Procleix Tigris Systems)
 - ✓ Procleix Auto Detect Reagents Kit (Procleix Panther System)

GRIFOLS

and, as a consequence, to register, notify, renew or modify the registration of medical devices in the territory of the Republic of Moldova according to the conditions of LAW No. 102 from 9 June 2017 regarding medical devices.

Date: 31 October 2024

Diagnostic Grifols, S.A.

Signature:

DocuSigned by:

Surgi Kowa Name: Sergi Roura Adell

Position: Proxy



Manufacturer's Statement

To: Centrul pentru Achizitii Centralizate in Sanatate.

Tender no. 21293399 - "Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național "Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025".

To Whom It May Concern:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain), hereby declare that the offered product Procleix Ultrio Elite assay fulfils all technical specifications as described in the

Procleix Ultrio Elite assay instructions for use & Procleix Ultrio Elite assay brochure

Date: 31 December 2024

Diagnostic Grifols, S.A.

Signature:

DocuSigned by:

Sergi Roura

Naffié: SergfRoura Adell

Position: Proxy



Manufacturer's Statement

To: Centrul pentru Achizitii Centralizate in Sanatate.

Tender no. 21293399 - "Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național "Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025".

To Whom It May Concern:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain), hereby declare that the offered product Procleix Panther system fulfils all technical specifications as described in the

Panther Operator's Manual & Procleix Panther System technical specifications brochure

Date: 31 October 2024

Diagnostic Grifols, S.A.

Signature:

DocuSigned by:

Sergi Rowa

Namensadell

Position: Proxy



Manufacturer's Statement

To: Centrul pentru Achizitii Centralizate in Sanatate.

Tender no. 21293399 - "Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național "Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025".

To Whom It May Concern:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain), hereby declare that each batch of the offered product Procleix Ultrio Elite Assay will be delivered with a specific Certificate of Analysis.

Date: 31 October 2024

Diagnostic Grifols, S.A.

Sergi Roura

Namensserge Roura Adell

Position: Proxy



Manufacturer's Statement

To: Centrul pentru Achizitii Centralizate in Sanatate.

Tender no. 21293399 - "Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național "Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025".

To Whom It May Concern:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain), hereby declare that the remaining shelf life (at the time of delivery) will be not less than 80% of the total shelf life of the product, i.e Procleix Ultrio Elite Assay.

Date: 31 October 2024

Diagnostic Grifols, S.A.

Signature:

- DocuSigned by:

Surgi Kowa Name: SergERoura Adell

Position: Proxy



Manufacturer's Statement

To: Centrul pentru Achizitii Centralizate in Sanatate.

Tender no. 21293399 - "Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național "Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025".

To Whom It May Concern:

I, the undersigned, Sergi Roura Adell, resident of Spain, holder of valid passport number PAN177411, acting as Proxy of **Diagnostic Grifols, S.A.**, a company duly incorporated and existing under the laws of Spain, having its registered address located at Polígono Levante, C/Can Guasch, s/n, 08150-Parets del Vallés, Barcelona (Spain), hereby declare that two identical Procleix Panther analyzers will be supplied, offering exactly the same performances.

Date: 31 October 2024

Diagnostic Grifols, S.A.

Signature:

DocuSigned by:

Surgi Kowa Ec39A4C99AA24E2... Name: Sergi Roura Adell

D ... D

Position: Proxy



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