

EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
 Passeig Fluvial, 24
 08150 – Parets del Vallès (Barcelona)
 Spain
 SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210600	Erytra Eflexis®	Erytra Eflexis® is a fully-automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing gel card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Compatibility Tests, and Direct Antiglobulin Tests. As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), Erytra Eflexis® automates test processing functions and data management requirements using Grifols gel cards and digital image processing.	843658373EFLEXISWN

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE IN CONFORMITY WITH THE REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS AVAILABLE UNDER THE PREMISES OF THE MANUFACTURER.

First emission date under IVDR:

December 15th, 2021

Place, Date of Issue:

Parets del Vallès, May 18th 2022

Signature:


 Albert Hernández Botey
 Technical Director
 Diagnostic Grifols, S.A.



/GRIFOLS logotipas/

DIAGNOSTIC GRIFOLS, S.A.
 Passeig Fluvial, 24
 08150 – Parets del Valles
 Barcelona – Ispanija
 Tel. (34) 935 710 400
 Faks. (34) 935 710 373
 diagnostic@grifols.com

ES ATITIKTIES DEKLARACIJA

Gamintojas: DIAGNOSTIC GRIFOLS, S.A.
 Passeig Fluvial, 24
 08150 – Parets del Valles (Barcelona)
 Ispanija
 SRN: ES-MF-000000784

Produktas (-ai):

Katalogo numeris	Pavadinimas	Numatytoji paskirtis	Pagrindinis UDI-DI
210600	Erytra Eflexis®	Erytra Eflexis® yra pilnai automatizuotas analizatorius, skirtas in vitro imunoematologinių žmogaus kraujo tyrimų automatizavimui panaudojant gelio kortelių technologiją, įskaitant kraujo grupių nustatymą, antigenų tipų nustatymą, antikūnų atranką, antikūnų identifikavimą, suderinamumo tyrimus bei tiesioginius antiglobulino tyrimus. Kaip atskiras analizatorius arba sujungtas su kliento laboratorijos informacine sistema (LIS), Erytra Eflexis® automatizuoja tyrimų apdorojimo funkcijas ir duomenų valdymo reikalavimus, naudodant Grifols gelio korteles ir skaitmeninį vaizdų apdorojimą.	843658373EFLEXISWN

Klasifikacija: A klasės prietaisai pagal IVDR ES 2017/746 VIII priedo 5 taisyklę.

DIAGNOSTIC GRIFOLS, S.A., PRISIIMDAMA VISĄ ATSAKOMYBĘ, TVIRTINA, JOG AUKŠČIAU MINIMAS PRODUKTAS ATITINKA ATITINKA 2017 M. BALANDŽIO 5 D. EUROPOS PARLAMENTO IR TARYBOS REGLAMENTĄ (ES) 2017/746 DĖL IN VITRO DIAGNOSTIKOS MEDICINOS PRIETAISŲ. VISI PATVIRTINAMIEJI DOKUMENTAI IŠLIEKA GAMINTOJO ŽINIOJE.

Pirmojo leidimo data pagal IVDR: 2021 m. gruodžio 15 d.

Leidimo vieta ir data: Parets del Valles, 2022 m. gegužės 18 d.

Parašas: /parašas/ /spaudas/
 Albert Hernandez Botey
 Techninės dalies direktorius
 Diagnostic Grifols, S.A.

Tikslus dokumento vertimas į lietuvių kalbą
 Vertėja A*
 Data
 UAB Diamedica
 Gėlių g. 2, Avižieniai, Lietuva

Erytra Eflexis software v3.2

Smart on-board stability tracking

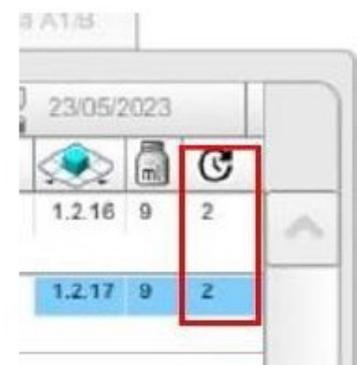
Feature

13p.

- Automatic management of reagent red blood cells stability for continuous on-board (24h a day/5 days)
- Begins countdown of remaining hours when vial loaded onto the instrument
- New icons in the user interface indicate:
 - When on-board stability has elapsed
 - Remaining hours of on-board stability
- Traceability tab and report indicates remaining on-board stability at time of test execution

Benefit to the customer

- Customer no longer required to use external manual solutions for on-board stability tracking to **increase safety** and **reduce hands-on time**
- Real-time, easily accessible information regarding the remaining on-board stability from the instrument, allowing for **better work-flow planning** in the laboratory
- **Evidence** of on-board stability at time of execution is helpful for audits and retrospective investigation of unexpected results





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erytra
eflexis[®]

Adaptability
that fits your lab



TYPING

erytra
eflexis[®]

No matter your workflow, the system addresses your changing needs

No two IH labs are alike; therefore, Grifols offers a scalable range of different instruments that are specifically tailored to suit different processing needs.

Now, we are introducing the new Erytra Eflexis, the natural evolution in Grifols scalable blood typing solutions.

Introducing the new Erytra Eflexis

Erytra Eflexis adaptability helps labs achieve workflow efficiency and improve daily work routines. The system provides reliable and timely results that contribute to patient safety.

This truly flexible system allows laboratories to select the solution that is best suited to different workflow needs and capacities.

Erytra Eflexis is a benchtop, compact model. The transparent casing and simple internal organization provide a clear view of the internal processes.

- Process status indicator traffic light
- External touchscreen can be placed on either side of the instrument

TOP PRIORITY

A primary concern in blood transfusions is patient safety. After fifty years of experience in the field of transfusion medicine, safety is also our number one priority. For more than twenty years, Grifols has driven innovation in developing blood typing systems that support safer transfusions all over the world.



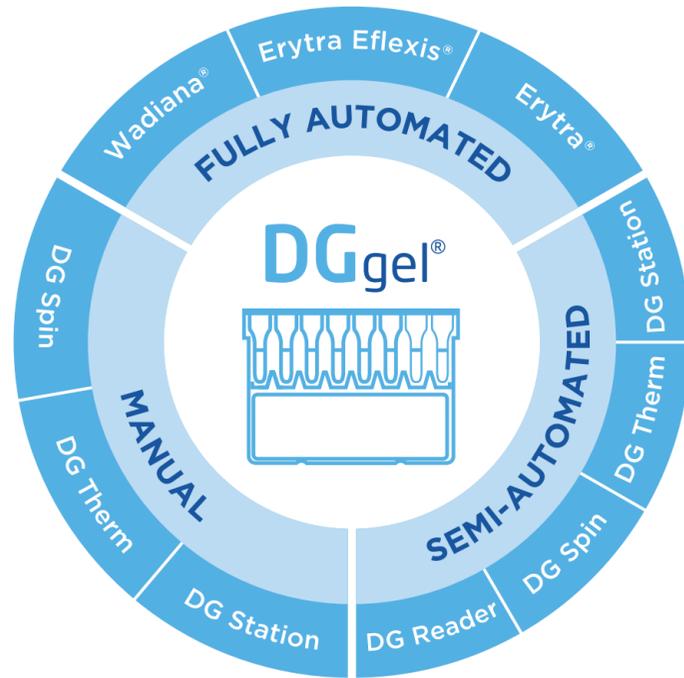
INTRODUCING

Erytra Eflexis is a fully automated, mid-sized analyzer that performs pretransfusion compatibility testing.

The system uses DG Gel technology with a smart and compact design offering intuitive operation.

Enjoy the virtual experience!

Explore the DG Gel® system portfolio and the new Erytra Eflexis by downloading the DG Gel augmented reality application. Enjoy the virtual experience!



Welcome to the virtual experience of DG Gel system.

Please download the DG Gel augmented reality application through the QR code. Scan the DG Gel target circle with your smartphone or tablet to begin the experience.



Download from



Download from



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eflexis®

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eflexis®

Technical specifications



LIST OF TECHNIQUES

Full ABO/Rh blood group typing (forward and reverse)
Rh + Kell phenotype
Antibody screen
Antibody identification
Enzyme assays
Antibody titration*
Direct Coombs test
Rare antigens typing
Weak D test
ABO/Rh (D) confirmation
Crossmatch test

*Feature under development

THROUGHPUT

Maximum throughput: 50 cards/hr (400 results/hr)¹
Full ABO/Rh blood group typing: 35 samples/hr²
Antibody screening (I, II, III): 72 samples/hr
Type & Screen: 23 samples/hr³

Throughput depends on the profiles being processed:

- 1 Results obtained with DG Gel® Rh Pheno + Kell
- 2 Results obtained with DG Gel® ABO/Rh (2D) (profile: A, B, AB, D1, D2, Ctl., N/A1, N/B)
- 3 Results obtained with DG Gel® ABO/Rh (2D) and antibody screening (I, II, III)

CAPACITY

2 lab configuration options:

- For peak hours:
 - 23 reagents (1 rack): 17 agitated, 5 non-agitated and 1 diluent (non-agitated reagents can be extended to 22)
 - 72 samples: 3 racks x 2 holders x 12 positions
- For more comprehensive menu:
 - 46 reagents (2 racks): 34 agitated, 10 non-agitated and 2 diluents (non-agitated reagents can be extended to 44)
 - 48 samples: 2 racks x 2 holders x 12 positions

Up to 200 DG Gel cards

Washing solutions:

- 6 L DG Fluid A solution (extendable to 12 L)*
- 6 L DG Fluid B solution (extendable to 12 L)*
- 12 L waste solution*

*With optional direct drainage to laboratory

SIZE AND WEIGHT

Width: 110 cm (without monitor) (43.3 in)
Depth: 71 cm (27.9 in)
Height: 91 cm (35.8 in)
Weight: Approximately 173 kg (381.4 lb)

POWER SUPPLY

Voltage: 100-240 V
Frequency: 50-60 Hz
Input power: 600 W

REFERENCE	PRODUCT LIST	PRODUCT DESCRIPTION
210600	Erytra Eflexis	A fully automated, mid-sized analyzer to perform the pretransfusion compatibility tests using DG Gel technology with a smart and compact design for intuitive operations
210601	Erytra Eflexis rack for samples	Rack to load samples into the Erytra Eflexis
234179	System solution container	Container designated to hold diluted wash solution (A or B) or decontamination solution
213713	Samples holder	Holder to load samples into the analyzer
210603	Erytra Eflexis card waste container	Disposable container for card waste

The Erytra Eflexis® analyzer is CE marked in accordance with the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Product registration and availability vary by country. Ask your local Grifols representative for more information.

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1 2 3 4

5

6



How can you benefit by using the Erytra Eflexis?

Employ highly flexible performance to optimize your lab

- Two in One – Two different lab configurations in a single instrument through the unique interchangeable sample and reagent lineal racks, automatically recognized by the system
- Excellent capacity of cards and samples for a mid-size analyzer, depending on the system configuration
- Flexible incubator management is available depending on the requested tests
- True continuous loading of cards, reagents, and samples

Reduce hands-on time with an intuitive user-friendly experience

- Minimal training¹ is required to interact with the easy-to-use external touchscreen
- Minimal maintenance²
- Remote access for results validation and after-sales support remote connection

Improve daily workloads and efficiency easily

- Multiple lab configurations as well as different multi-site health networks can be tailored – the system can be easily used alone or connected to other Erytra Eflexis or Erytra units
- Always sharing the same:
 - Our latest generation software suite
 - Sample holders
 - Convenient Grifols universal reagents³

Grifols exclusive simultaneous perforation and dispensing technology enable 100% use of the cards

19 punktas

100%

use of cards across
all Grifols platforms

100% kortelių naudojimas
visose Grifols platformose.

Išskirtinė Grifol viena laikio perforavimo ir dozavimo technologija leidžia 100% naudoti korteles

¹ The training required is similar to the training for the Erytra instrument

² Only monthly maintenance is required

³ Grifols universal reagents are compatible to work with all of the DG Gel system platforms (from manual to fully automated instruments)

2 in 1



OPTION 1

A comprehensive menu:

48 samples

46 liquid reagents

High sample
capacity for a
mid-size system



OPTION 2

During peak hours:

72 samples

23 liquid reagents

A smart, compact design for optimal use of lab space

Samples & reagents management — Flexible performance with easy adaptability for different workflow needs

- Internal backup
- STAT management — just load the samples randomly in any position, click the STAT button and samples will be automatically prioritized
- Continuous and random loading and unloading of samples and reagents
- Fast positive identification

2

independent centrifuges
(12 cards/centrifuge)

3

intelligent incubators
independently managed
(12 cards/incubator)

Grifols exclusive
probe system



- Lab workflow adaptability — unique interchangeable sample and reagent lineal racks automatically identified by the system
- To hold any type of tube, including pediatric tubes or those with plungers, the same Erytra sample holders are used providing additional flexibility
- Clever maintenance of the red blood cell reagent suspension
- Multi-functional pipettor arm using Grifols exclusive probe system, which accounts for several functions like:
 - Automatic level detection and fluid level monitoring
 - Sample dilution by using the Grifols universal DG Gel Sol diluent in the cup dilution station (automatic washing)
 - Unique simultaneous perforation and dispensing technology uses 100% of the card wells and prevents cross-contamination
 - Integrated probe washing station to prevent cross-contamination

CAPACITY UP TO

72 samples

46 liquid reagents



Flexible performance

DG Gel card management — Extensive capacity to store up to 1600 tests

- Exclusive direct loading of the DG Gel double decker racks on the Grifols multi-drawer system
- Fast positive identification
- High stock and monitoring of 8-well DG Gel cards
- Flexible incubation and centrifugation
- High-resolution reading with a multi-functional CCD camera:
 - Card integrity check before and after processing
 - Dispensing verification of the DG Gel cards
 - High-definition color results

System solutions management — Easy user interaction

- Monitoring of the level of Erytra Eflexis solutions and the number of cards used
- Easy and innovative loading and unloading of system fluids allow for minimal user interaction
- Optimal direct drainage to maximize system's autonomy
- New disposable cards waste container supports user safety

CAPACITY UP TO

200 cards (1600 tests)

Universal washing
solutions used
by all Grifols
platforms



DG Gel cards loading area



System solutions area

Intuitive experience

Simply load, select, and process!

The Erytra Eflexis may be easily operated by all grades of staff after minimal training.

User intervention is minimal. The software is user-friendly and intuitive yet rich in detail and customizable.

REAL-TIME INFORMATION

- Analyzer status and available autonomy
- Time to results
- Real-time system alerts

CLEAR RESULTS

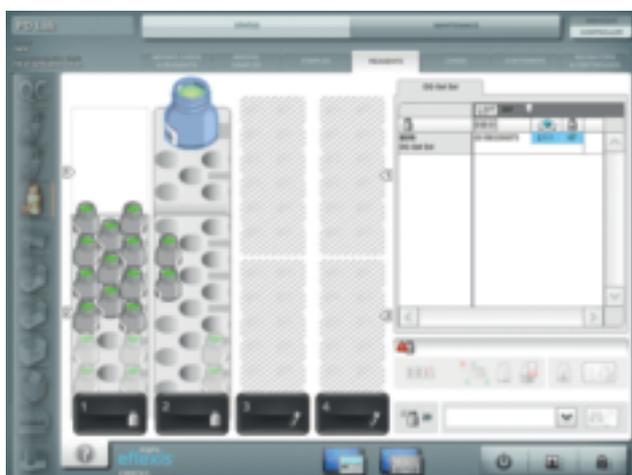
- Revision of results with a clear, close-up, high-definition picture for extra assurance
- Check of discrepancies. Configurable warnings for results to be reviewed
- Complete results traceability report

INCREASED SAFETY AND SECURITY LEVELS

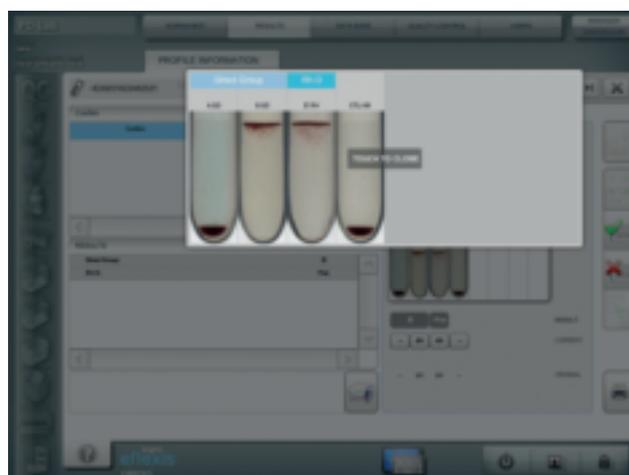
- Entire process and results are fully traceable
- System access is password controlled. Configurable roles per user
- Continuous monitoring of all critical processes
- Configurable quality control policy

EFFICIENT COMMUNICATION

- Bidirectional connectivity to the LIS (laboratory information system)
- Remote access to the instrument through the web application to validate results, monitor instrument and samples status and real-time warnings
- Remote diagnostics: technical/specialist support can remotely connect to the system for troubleshooting



Real-time information



Clear results



erytra
eflexis®

GRIFOLS

101 201 301

Erytra Eflexis priežiūros žurnalas

Istaiga

Analizatoriaus serijos numeris:

Metai:

Mėnuo:

<i>Kas savaitę</i>					
Diena					
• Paviršių nuvalymas (jei reikia) (~5 min)	Atlikta <input type="checkbox"/>				
• Analizatoriaus perkrovimas (~ 10 min)	Atlikta <input type="checkbox"/>				
Parašas					

<i>Kas mėnesį</i>	
Data	
• Analizatoriaus ir jo komponentų nukenksminimas (~2 val)	Atlikta <input type="checkbox"/>
• Skysčių konteinerių nukenksminimas (~10 min)	Atlikta <input type="checkbox"/>
Parašas	

<i>Prireikus</i>				
Data				
• Medžiagų išsiliejimo vietų išvalymas (~iki 5 min)	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>
• Patikrinti ar nėra skysčių nuotėkių be mikroorganizmų augimo (~iki 5 min)	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>	Atlikta <input type="checkbox"/>
Parašas				

- Išsamios informacijos apie priežiūros procedūras žr. Erytra Eflexis naudojimo instrukcijos skyriuje „Priežiūra“