Grifols receives first certifications for new In Vitro Diagnostics Medical Devices European Regulation

- ***Initial certifications obtained for broad product range including Promonitor Quick IFX, one of the first near-patient testing devices approved under the In Vitro Diagnostics Medical Devices Regulation (IVDR)***

- ***Grifols, committed to continously enhance the quality and safety of its solutions, is on track to be fully compliant with IVDR, a mandatory requirement for products to be CE-marked***

Barcelona, Spain, December 2, 2021 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global leader in the development of plasma-derived therapies and innovative diagnostic solutions, today announced it has received its first European Union (EU) Technical Documentation Assessment and Quality Management System certificates under the In Vitro Diagnostics Medical Devices Regulation (IVDR) from the TÜV SÜD Product Service and from BSI, both of which are EU-designated notified bodies under the new regulation.

Manufacturers of in vitro diagnostic devices are required to certify their products according to the new European Commission safety, quality and regulatory standards scheduled to take effect in May 2022. The transition period for devices certified under the existing directive, IVDD, is currently under revision by the European Parliament.

Grifols has achieved IVDR certifications for a broad range of products for immunohematology blood typing and detection of anti-erythrocyte antibodies, such as DG Gel cards, antisera, reagent red blood cells and ID HPA XT test, a human platelet antigen (HPA) genotyping assay.

The company also received certifications for the Promonitor portfolio, used in patients receiving biological therapies to treat chronic inflammatory diseases, including the Promonitor ELISA family and Promonitor Quick. Promonitor Quick IFX, for measuring infliximab levels, is one of the first near-patient testing devices of any manufacturer approved under the IVDR.

The company also received IVDR certifications for its alpha-1 antitrypsin deficiency (A1AT) genotyping test, designed to detect simultaneously 14 of the most prevalent known allelic variants associated with A1AT.

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"As part of its continuous commitment to the highest standards to ensure patient safety and meet customer needs, Grifols will ensure that all its products requiring IVDR certification will receive it on time," said David Dew, President, Diagnostic Commercial Division.

During 2020 Grifols began submitting product documentation to the Conformity Assessment Bodies for IVDR certification from areas including immunohematology blood typing, infectious disease blood screening and clinical diagnostic.

About IVDR

Since 1998, Directive 98/79/EC (referred as IVDD) has regulated and still regulates in vitro diagnostic devices (IVD) that are placed on the European Union (EU) market. This legislation, which aims to ensure that IVDs are fit for the defined purpose and reliably provide information to be used for diagnostic purposes, is being replaced by the new EU Regulation 2017/746 (referred as In-vitro Device Regulation [IVDR]) with date of application on 26 May 2022. While the IVDD classifies the IVD products into three categories (Annex II List A, Annex II List B and non-Annex II listed), the IVDR uses four new categories (A, B, C and D). Under the new IVDR, products classified into classes B, C and D require certification by a conformity assessment body (i.e. Notified Body) in a similar way that this is a requirement for those products listed in Annex II (List A and B) of the IVDD. As per today's effective timing, a transition period for those IVDs that are certified by a Notified Body under the current Directive may last until at least May 2024. Nevertheless, a new IVDR amendment, pending approval from the European Parliament, proposes a longer grace period for devices covered by a certificate issued under IVDD, including self-declared devices. .

About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 100 countries.

Pioneers in the plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat chronic, rare and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion. In addition, the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with nearly 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2020, Grifols' economic impact in its core countries of operation was EUR 7.5 billion. The company also generated 140,000 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information, please visit www.grifols.com

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