

SGS designated as a Notified Body under EU IVDR

GENEVA, SWITZERLAND, April 23, 2025 /EINPresswire.com/ -- SGS, the world's leading testing, inspection and certification company, is delighted to announce the designation of SGS Belgium NV as a Notified Body (NB) under the EU's In Vitro Diagnostic Medical Device Regulation (EU 2017/746, IVDR).

The Antwerp-based facility (Notified Body 1639) gained approval from the European Commission and Belgian Competent Authority (FAGG/AFMPS) on April 23, 2025.

EU IVDR aims to enhance the quality of patient care by safeguarding device safety and performance through the greater regulation of in vitro diagnostic medical devices placed on the EU market.



GS Belgium NV has been designated as a Notified Body under EU IVDR

With limited NB capacity in Europe emerging as a key challenge to implementing the new regulation, SGS's new team of IVD industry and clinical laboratory experts aims to ease the pressure on device manufacturers seeking CE marking for their in vitro diagnostic medical devices.

Geofrey De Visscher, Head of SGS NB 1639, said: "Thanks to the team's hard work, we are delighted to become a designated NB under the EU IVDR.

"We are excited to work with the industry to drive the implementation of this demanding regulation. With our existing approvals under the UK Conformity Assessed (UKCA) scheme, we are one of the few companies capable of providing certification services for medical devices

across the whole of Europe.

"Our team continues to rapidly expand to ensure that we can quickly serve the certification needs of our customers."

SGS Belgium NV is now listed in the European Commission's New Approach Notified and Designated Organisations (NANDO) database here.

SGS medical device regulatory compliance

SGS has decades of expertise in medical device regulatory compliance, providing a multitude of services, including EU Medical Device Regulation (MDR), ISO 13485 and Medical Device Single Audit Program (MDSAP) solutions. SGS NB 1639 and its global network of national offices are committed to supporting the industry on its IVDR compliance journey.

For more information, visit: https://www.sgs.com/en/services/in-vitro-diagnostic-medical-device-regulation-ivdr-certification-services

About SGS

SGS is the world's leading Testing, Inspection and Certification company. We operate a network of over 2,500 laboratories and business facilities across 115 countries, supported by a team of 99,500 dedicated professionals. With over 145 years of service excellence, we combine the precision and accuracy that define Swiss companies to help organizations achieve the highest standards of quality, compliance and sustainability.

Our brand promise – when you need to be sure – underscores our commitment to trust, integrity and reliability, enabling businesses to thrive with confidence. We proudly deliver our expert services through the SGS name and trusted specialized brands, including Brightsight, Bluesign, Maine Pointe and Nutrasource.

SGS is publicly traded on the SIX Swiss Exchange under the ticker symbol SGSN (ISIN CH0002497458, Reuters SGSN.S, Bloomberg SGSN:SW).

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