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PAXgene Blood ccfDNA Tube (CE-IVD) and QIAsymphony PAXgene Blood ccfDNA Kit (CE-IVD) CE Marked Under the EU In Vitro Diagnostics Regulation (IVDR)

Dear Valued Customer,

PreAnalytiX GmbH is proud to inform you that the PAXgene® Blood ccfDNA Tube (CE-IVD) is now CE marked for In Vitro Diagnostic use according to the Regulation EU 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) and will be available with the existing catalog number (cat. No. 768165; CE 0123) in early 2022.

The new QIAsymphony PAXgene Blood ccfDNA Kit (CE-IVD), CE marked for In Vitro Diagnostic Use according to the EU IVDR 2017/746, is compatible with both the currently available CE-IVD version according to the In Vitro Diagnostic Directive 98/79/EC (IVDD) and the upcoming CE-IVD version of PAXgene Blood ccfDNA Tube (CE-IVD) according to the IVDR.

In support of this product launch, PreAnalytiX has received the EU Quality Management System (QMS) Certificate pursuant to Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR), Annex IX Chapters I and III (Class A Devices in Sterile Condition) from the EU Notified Body TÜV SÜD in April 2021. This IVDR QMS Certificate will support all CE marked Class A Sterile PAXgene IVD blood collection tubes as they transition into compliance with the EU IVDR 2017/746.

Development of the tube and kit, as well as verification and validation of pre-analytical steps, including blood collection with stabilization, transport, storage, plasma preparation, ccfDNA isolation from plasma and gDNA isolation from the cellular fraction, were conducted and documented according to the International Standard ISO 20186-2:2019 and ISO 20186-3:2019, "Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA" and "Part 3: Isolated circulating cell free DNA from plasma," to ensure standardization of the workflow, integrity of the supporting data for the products and state-of-the-art requirements under the IVDR.

On May 26, 2022, the five-year transitional period for the new EU Regulation on In Vitro Diagnostic Medical Devices (IVDR 2017/746) will end. PreAnalytiX is actively fulfilling its commitment to timely certification of its In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD) portfolio to the EU IVDR 2017/746. Furthermore, in addition to complying with regulatory requirements, we consistently strive to meet our customer's needs by ensuring the continuous availability of all of our products for medical professionals and patients alike. More information about the IVDR is available at www.qiagen.com/IVDR-support.

Best regards,

PreAnalytiX