

Customer Notification

CN - 2023 / 29

Date: 11th of May, 2023

To: Microgen portfolio customers Subject: Microgen product line change

Dear Partner,

We would like to inform you about a change related to Microgen products.

For details, please see information below.

INFORMATION

Description of the change:

The products related to Microgen product line will be produced, QC tested and released in GSD Budapest plant by applying the established product acceptance criteria in order to meet the original product specification.

Effect on Quality:

To ensure that, those products will go through robust production and quality processes and controls that are part of GSD Budapest Quality Management System meeting ISO 9001 and 13485 standards.

In addition, the production transfer will be managed following sound project management practices aimed at ensuring a smooth execution while mitigating any risk identified.

In case of any further questions, please contact Gold Standard Diagnostics Budapest's Customer Support.

Yours Sincerely,

Quality Assurance