An ISO Certified Company

Change Notification regarding CE-IVD marked Plasticware/Labware of Tarsons

Dear Valued Customers and Users,

This is to inform you about a recent change that is being implemented for our product portfolio marked with CE-IVD. Tarsons has already discontinued marking 'CE-IVD' for the following product categories:

Microtips and Macrotips; Cryo Vials and Storage Vials; Centrifuge Tubes; Pasteur Pipettes; PCR Tubes, Strips, and Plates; Petridish, Contact Plates and Micro test plates; Micro Centrifuge tubes.

Tarsons products were self-certified and registered as IVD products as per IVD directive 98/79/EC. However, from May 2022, the new EU IVD Regulation 2017/746 replaces the current IVD Directive 98/79/EC.

The new IVD Regulation (2017/746) provides better clarity about the classification of *in vitro* diagnostic medical devices. As per new IVDR, Tarsons products are identified as general laboratory items that can be used for various *in vitro* diagnostic applications although these are not related to one specific IVD application or examination, hence it can't be classified as IVD. (Refer to Annex VIII, Rule 5 of IVD Regulation 2017/746)

The above product categories without CE IVD mark will still be suitable for all general laboratory applications including IVD applications as these will be manufactured with the same ISO 9001 & ISO 13485 certified Quality Management systems and will be identical to previously 'CE-IVD' marked products in all aspects. The 'CE-IVD' marking of product labels has already been discontinued, remaining stock will be sold until stock lasts and following the transitional provision of the new IVDR.

For Tarsons Products Ltd.

TARSONS PRODUCTS LIMITED HOWRAH

SANJIB DEY. PhD
Senior Manager- Quality Assurance

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