

## **NEW WORK ITEMS PROPOSED**

A Preliminary Work Item has been tabled on **Manufacturers' considerations for in vitro diagnostic medical devices in a public health crisis**. This document will be developed as a Technical Specification and is out for voting until 13 March.

## **NEW WORK ITEMS ACCEPTED**

Revision of EN 14180\_2014 Sterilisers for medical purposes – low temperature steam and formaldehyde sterilisers – requirements and testing

ISO/TC 212 N 901 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 1: Isolated RNA

ISO/TC 212 N 902 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 2: Isolated DNA

ISO/TC 212 N 903 Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 3: Preparations for analytical CTC staining

## STANDARDS TO BE REVISED OR OUT FOR REVIEW

None

## **DRAFT STANDARDS**

IEC TR 62586-3 Ed1 Power quality measurement in power supply systems, Part 3: Maintenance tests, calibration has been circulated as a draft for comment until 13 May 2022.

EN 62423:2012 Type F and type B residual current operated circuit-breakers with and without integral overcurrent protection for household and similar uses is out for voting until 22 April 2022.

**IEC TR 60878 ED4 Graphical symbols for electrical equipment in medical practice** is out for voting until 18 March.

EN ISO 8536-3:2009/prA1 Infusion equipment for medical use - Part 3: Aluminium caps for infusion bottles - Amendment 1 has been approved at enquiry stage.

prEN ISO 8872 Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials - General requirements and test methods has been approved at enquiry stage.

FprCEN/TS 17747: Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins has been approved.

ISO 3826-1:2019/CD Amd 1 Ballot type CD Ballot title Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers — Amendment 1 has been approved.

**prEN ISO 15189 Medical laboratories - Requirements for quality and competence** has been approved at enquiry stage.