

Certificate of conformity

EN 10204 – 2.1

We hereby certify that the

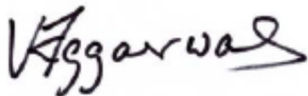
electrolyte solution for the pH Reiner probe (part number 595925-)

is suitable for contact with food.

The main ingredient of the electrolyte solution is water for injection purposes according to the European Pharmacopeia. The potassium chloride (KCl) used also corresponds to the quality required by the European Pharmacopeia. It is licensed according to the Food Chemical Codex (FCC) and classified as "Generally recognized as safe" according to the FDA – Code of Federal Regulations under title 21CFR184.1622.

The water used is examined daily for its chemical-physical and microbiological quality. The manufacture and filling of the products takes place in a classified and monitored clean room with cleaned equipment. The product is subject to comprehensive batch documentation and is made exclusively from tested and cleared raw materials. The manufacturer's operating facilities are monitored regularly in accordance with § 64 Pharmaceutical Products Act (AMG) and are subject to the Ordinance on the manufacture of pharmaceutical products and active pharmaceutical ingredients for application of good manufacturing practice in the manufacture of pharmaceutical products and active ingredients.

Pfaudler GmbH
Quality Assurance



Vinod Aggarwal,
Quality Manager

Schwetzingen, 20.07.2017

HB025E

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