

Certificate

Gamma irradiation and X-ray irradiation

We hereby certify that, in the case of the following products

GEMÜ SUMONDO® single-use diaphragm valves

no negative impact attributable to gamma irradiation and X-ray irradiation was detected during the mechanical stress tests performed as part of product validation and during the extractables study.

Product validation and the extractables study were carried out on SUMONDO® single-use diaphragm valves which were previously irradiated with a dosage of 50 kGy in compliance with ISO 11137.

Disclaimer:

GEMÜ shall not accept any responsibility for the faultless functionality of the SUMONDO® single-use diaphragm valves after gamma or X-ray sterilization has been performed by the customer or an external service provider, as the radiation dosage, storage conditions (temperature, time period) and operating conditions are outside the sphere influence of GEMÜ.

Maximilian Barghoorn
Head of Global Technics
Ingelfingen 29-08-2023

This document is valid without signature.