According to the requirements of the European Medical Device Directive (MDD), respectively from 05/2021 the Medical Device Regulation (MDR) the cleaning of medical devices has to be validated. Validation means that the process

1. has to be effective and
2. must not change unnoticed later on during daily use, that means, it has to work reproducibly.

Therefore in automatic cleaning processes all parameters must be monitored to secure the reproducibility in washer/disinfectors (WDs). The parameters must not change unnoticed. Some process information is already provided by the WD itself using its integrated temperature and time gradient recording system. Some WDs also measure the dosage amount of the detergent and/or the rotation speed of the spray arms.

The following critical parameters cannot be monitored by WDs themselves:

1. Changes of the water quality, e.g. of water hardness, salt content, etc.
2. Wrong selection of the detergent (mix-up of canisters)
3. Use of an expired detergent with less cleaning efficacy
4. Selection of a wrong program (for the load)

To be able to monitor these parameters not monitored by the WD, GKE has developed artificial test soils to be placed as cleaning process monitoring indicators (CPI) in the process and visually check their wash-off extent after the cleaning process.

The indicators are offered in different wash-off difficulty levels, so that for each individual cleaning process the suitable indicator can be selected.

The recommendation for monitoring of medical devices of the Robert Koch Institute (RKI) mentions “cleaning indicators”. Today the term “cleaning process monitoring indicator” (CPI) is being used, which is more precise. Generally cleaned instruments have to be optically checked for visible remaining soils on their surfaces. If complex instruments have been cleaned, the optical check may not be possible because inner surfaces – e.g. in hollow lumens – are not visible. In this case the RKI recommendation recommends to use adequate “cleaning indicators” which are added to the process.

It is not mentioned how many CPI should be used, this depends individually on the load, the cleaning inhomogeneity in the chamber and the chamber size. Since malfunctions in the cleaning process can happen anytime and without warning, the CPI are mentioned in annex 3 under “batch-related tests” of the RKI recommendation of October 2012 which is about the operation of WDs. The use of CPI is therefore not suitable for sampling tests but part of the continuous batch monitoring and product release.