

Notification by the Disinfectants Commission
of the German Association of Applied Hygiene (VAH)



Requirements for VAH listing of surgical hand disinfectants

Technical information for applicants and laboratories

As of 10 September 2021

Efficacy testing of surgical hand disinfectants: simulated-use testing with subjects

In 2016, EN 12791:2013-07 regulating surgical hand disinfection was revised and the number of subjects and statistical evaluation were updated in European consensus. This was already pointed out in *Method 12* of the *Requirements and Methods* for VAH certification published in 2015, with the recommendation to increase the number of subjects [1].

The revision was implemented in 2016 and the previous version has now been replaced with EN 12791:2018-01 [2].

This has resulted in **the following important changes** to simulated-use testing with subjects:

- The number of subjects has been increased to between 23 and **28 subjects**, whereby evaluable results must be available for at least 23 subjects.
- Efficacy testing of the immediate effect and the 3-hour effect is performed in accordance with Hodges & Lehmann. The test product (TP) must not be inferior to the reference product (RP). A one-sided significance level of $\alpha = 0.025$ is applied.
- The inferiority margin is 0.75 lg for the immediate effect and 0.85 lg for the 3-hour effect.
- If a sustained effect is to be claimed, the results of the Wilcoxon paired-samples signed-rank test must also be reported with a one-sided significance test of $p = 0.01$.

The Disinfectants Commission therefore decided that from **1 January 2022** for surgical hand disinfection only those test reports that comply with the currently valid EN 12791:2018-01 or with the *Requirements and Methods* for VAH certification of chemical disinfection procedures from 2022, which are currently under revision, will be accepted.

If results are available which are based on the previous version of EN 12791 or on the *VAH Methods Book* from 2015, these can be supplemented by conducting tests with additional subjects (preferably in the same laboratory). Statistical evaluation of the old and new data is then performed based on the new method in accordance with Hodges & Lehmann.

For **recertifications** or **new listings**, this should be taken into account in advance **when submitting the application**.

References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Requirements and Methods for VAH certification of chemical procedures. (2015). mhp Verlag: Wiesbaden. https://vah-online.de/files/download/ebooks/eBook_VAH_RequirementsandMethods.pdf
2. Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2); DIN EN 12791:2018-01

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