

BIDDER DECLARATION – Compliance Statement Product qualification

Tender title: _____

Procurement of essential medicines for action medeor labworks for warehouse Tönisvorst

Tender No.: _____

AML-TV-M-2026-10

The undersigned bidder declares:

That the product (s) complies/comply with the latest prequalification documentation submitted to action medeor labworks to comply with applicable laws and the ethical standards and code of conduct of action medeor labworks GmbH

Product name	Quality documentation date or reference number

The bidder acknowledges to inform action medeor labworks about any important changes which may lead to a change in the prequalification status, such as:

- Change in the GxP status of supplier
- OOS findings in ongoing stability studies
- Change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is available
- deletion of Ph. Eur. certificate of suitability
- Change in pharmacopeial grade of an active substance

- Change in the specification parameters and/or limits of an excipient classified as high-risk excipient
- Change in test procedure for an excipient classified as high-risk excipient
- Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product
- Changes in the composition (excipients) of the finished product
- Change in the specification parameters and/or limits of the finished product
- Change in test procedure for the finished product
- Change in immediate packaging of the finished product
- Change in the shelf-life or storage conditions of the finished product
- Change in the marketing authorization status, especially if an existing authorization expires or is withdrawn

Bidder: _____

Place/Date: _____

Authorised signature:
