DECLARATION OF PRODUCT REFERENCE CORRESPONDENCE AND TRACEABILITY

Manufacturer:

MA-COM d.o.o.

Stolac, Bosnia and Herzegovina

1. Purpose of the Declaration

This Declaration is issued to establish and document traceability between the previously used customer/distributor references and the corresponding official MA-COM product references for IVD products previously placed on the market.

This Declaration shall be read in conjunction with the applicable MA-COM Declaration of Conformity for the IVD products concerned:

Declaration of Conformity: Declaration of Conformity for Specimen Containers
Revision/Version: 10.0

2. Product Reference Equivalence

MA-COM d.o.o. hereby confirms the following correspondence between the previously used customer/distributor references and the official MA-COM product references:

Previously Used Customer/Distributor Reference	Official MA-COM REF / Catalogue Number
SE0201	1355
SE0202	1355-BP
SE0202-50	1355-BP-50
SE0203	1541
SE0203-50	1541-50
SE0204	1340

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The SE0 references listed above were customer/distributor-specific commercial article references used for the corresponding MA-COM products.

The listed SE0 references do not represent separate MA-COM product references.

3. Changes to Product Identification and Labelling

In May 2025, MA-COM updated its product labelling in accordance with the applicable requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), particularly the requirements relating to product identification, the UDI system and traceability.

The update included the addition of the official MA-COM REF (catalogue) number to ensure a clear link between the product, its UDI, the applicable Declaration of Conformity and the corresponding technical documentation.

Subsequently, as of October 2025, the previously used customer/distributor references beginning with “SE0” were replaced by new customer/distributor references beginning with “EDHA”.

Consequently, products placed on the market before these changes may still bear the previously used SE0 customer/distributor references, and the MA-COM REF number may not be displayed on them in the same manner as on the current product labelling.

4. Traceability of Products Remaining on the Market

Certain products bearing the previously used SE0 references remain on the market within their declared shelf life.

These products were lawfully placed on the market during the period in which the relevant Declaration of Conformity was applicable, and their declared shelf life has not yet expired.

The difference in product references does not affect the identity, intended purpose, composition, quality, safety, performance or regulatory status of the products.

This Declaration is issued solely for the purpose of identifying and ensuring the traceability of such products and establishing the documented link between:

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Previously Used SE0 Customer/Distributor Reference → Official MA-COM REF/Catalogue Number → Applicable MA-COM Declaration of Conformity

The products identified by the previously used SE0 customer/distributor references listed in Section 2 correspond to the respective MA-COM products identified by the official MA-COM REF/catalogue numbers stated in the same table.

5. Regulatory Status

This Declaration serves exclusively as a supporting identification and traceability document for products previously placed on the market under the previously used SE0 customer/distributor references and which remain within their declared shelf life.

It does not constitute a new Declaration of Conformity and does not replace, amend or extend the scope of the referenced MA-COM Declaration of Conformity.

The applicable MA-COM Declaration of Conformity and the corresponding technical documentation remain the governing regulatory documents for the products identified by their official MA-COM REF/catalogue numbers.

Place: Stolac, Bosnia and Herzegovina
Date: 11 September 2026

For and on behalf of MA-COM d.o.o.

Name: Sanda Kolobara
Position: Quality Manager
Company stamp:



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