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| Original to:mdc medical device certification GmbHKriegerstraße 670191 StuttgartE-Mail: batch.release@mdc-ce.de | **For function tests only**, copy to: Paul-Ehrlich InstitutPrüflabor für In-vitro-Diagnostika (PEI-IVD)Paul-Ehrlich-Straße 51-5963225 LangenAdvance copy by Fax +49 6103-77-123 (without annexes) |

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|  | Customer number       |
| Legal name and address of the company      |
| Contact person      |
| Street      | Postal code, City            |
| Country      | E-Mail-Adress      |
| Phone      | Fax      |

Herewith we apply for the conduction of the inspection of the manufactured products according to Annex IV.6 of Directive 98/79/EC. This contract is based on the general terms of business of mdc medical device certification GmbH including the according price list and certification rules which we herewith accept.

**The following documents are mandatory to provide:**

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| to mdc:  | to PEI-IVD: |
| * Documentation of internal lot release
* For OEM-PLM: Decision of notified body of OEM and decalaration of product/lot identity
* Complete labeling and instruction for use
 | * Complete batch release documentation
* Sample (original product in agreed amount)
 |
|  **Applied inspection scope:** [ ]  Establishment of test criteria for batch release (3 independent lots)[x]  Routine test (1 lot)[ ]  Routine test (1 lot, reduced quantity acc. EK-MED 3.9.8 E14)[ ]  Routine test (1 lot, reduced, re-labelling)[ ]  Routine test (1 lot, reduced “OEM-PLM”-procedure) |
| Product name and article number (if applicable) |       |
| Blood group antigens, orinfection markers to be detected |       | For blood group testsused clone(s):  |
| Lot(s)\* | 1.      | 2. (only for establishment of test criteria)      | 3. (only for establishment of test criteria)      |
| Date of manufacture |       |       |       |
| Expiry date |       |       |       |
| \* mark the lot to be released in the course of establishment of test criteria |

Order placed:

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|       |
| (Date, stamp, authorized signature of the manufacturer) |