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| Original to:  mdc medical device certification GmbH  Kriegerstraße 6  70191 Stuttgart  E-Mail: [batch.release@mdc-ce.de](mailto:batch.release@mdc-ce.de) | **For function tests only**, copy to:  Paul-Ehrlich Institut  Prüflabor für In-vitro-Diagnostika (PEI-IVD)  Paul-Ehrlich-Straße 51-59  63225 Langen  Advance 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)  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, or  infection markers to be detected |  | | | For blood group tests  used 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) |