

## Declaration of Conformity

Konformitätserklärung / Déclaration de Conformité  
Declaration of Conformity / Dichiarazione di Conformità

|                                |                                |
|--------------------------------|--------------------------------|
| Name und Adresse der Firma     | Müller - Omicron GmbH & Co. KG |
| Nom et adresse de l'entreprise | Schlosserstr. 1, Industriepark |
| Nome e indirizzo della ditta   | D-51789 Lindlar                |
| Name and address of the firm   |                                |

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que  
Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

|                                                                                            |                                    |                            |                                              |
|--------------------------------------------------------------------------------------------|------------------------------------|----------------------------|----------------------------------------------|
| das Medizinprodukt<br>le dispositif médical<br>the medical device<br>il dispositivo medico | Produktbezeichnung<br>Siehe Anlage | Typ/Größen<br>Siehe Anlage | Artikelnummern der Varianten<br>Siehe Anlage |
|--------------------------------------------------------------------------------------------|------------------------------------|----------------------------|----------------------------------------------|

## Desinfektionsmittel für Medizinprodukte / Disinfection material for medical device

der Klasse / de la classe / della classe / of class IIa, Regel 15  
Nach Anhang IX der Richtlinie 93/42/EWG / selon l'annexe IX de la directive 93/42/CEE /  
secondo l'allegato IX della direttiva 93/42/CEE / according to annex IX of direct. 93/42/EEC

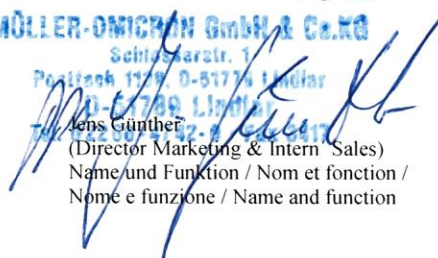
allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind /  
remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE qui le concernent / soddisfa tutte le disposizioni della  
direttiva 93/42/CEE che lo riguardano /  
meets all the provisions of the directive 93/42/EEC which apply to it.

|                                                                                                                                                                                                                                                                                                                                                 |                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Angewandte harmonisierte Normen, nationale<br>Normen oder andere normative Dokumente<br>Normes harmonisées, normes nationales et<br>autres documents normatifs appliqués<br>Norme armonizzate o nazionali applicate,<br>altri documenti normativi applicati<br>Applied harmonised standards, national<br>standards or other normative documents | DIN EN ISO 13485                                                                                            |
| Konformitätsbewertungsverfahren<br>Procédure d'évaluation de la conformité<br>Procedimento di valutazione della conformità<br>Conformity assessment procedure                                                                                                                                                                                   | Anhang II der Richtlinie 93/42/EWG                                                                          |
| Konformitätsbewertungsstelle (falls beigezogen)<br>Organe resp. de l'évaluat. de la conformité (si consulté)<br>Organo incaric. della valutaz. della conform. (se consultato)<br>Notified Body (if consulted)                                                                                                                                   | ECM Zertifizierungsgesellschaft für Medizinprodukte in Europa<br>GmbH<br>Bismarckstraße 106<br>52066 Aachen |

Lindlar, 01.06.2016

Ort, Datum / Lieu, date / Luogo, data / Place, date

Gültig bis: 08.06.2019  
Valid until: 08.06.2019



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Jens Günther  
(Director Marketing & Intern. Sales)  
Name und Funktion / Nom et fonction /  
Nome e funzione / Name and function

| REF        | Products                      | Packaging                               |
|------------|-------------------------------|-----------------------------------------|
| 701000094  | Dentalrapid AF Neutral,       | 100 ml fl.                              |
| 701000090  | Dentalrapid AF Neutral,       | 500 ml fl.                              |
| 701000591  | Dentalrapid AF Neutral,       | 5 L. can.                               |
| 701000970  | Dentalrapid AF Neutral,       | 500 ml spraybottle empty + spray nozzle |
| 701000099M | Dentalrapid AF Lemon,         | 100 ml fl.                              |
| 701000088  | Dentalrapid AF Lemon,         | 500 ml fl.                              |
| 701000599  | Dentalrapid AF Lemon,         | 5 L. can.                               |
| 701000990  | Dentalrapid AF Lemon,         | 500 ml spraybottle empty + spray nozzle |
| 701000040  | Dentalrapid AF Fruit,         | 100 ml fl.                              |
| 701000045  | Dentalrapid AF Fruit,         | 500 ml fl.                              |
| 701000541  | Dentalrapid AF Fruit,         | 5 L. can.                               |
| 701000940  | Dentalrapid AF Fruit,         | 500 ml spraybottle empty + spray nozzle |
| 701000050  | Dentalrapid AF Flower,        | 100 ml fl.                              |
| 701000055  | Dentalrapid AF Flower,        | 500 ml fl.                              |
| 701000551  | Dentalrapid AF Flower,        | 5 L. can.                               |
| 701000930  | Dentalrapid AF Flower,        | 500 ml spraybottle empty + spray nozzle |
| 701000092  | Dentalrapid AF Wipes Neutral, | 1 box with 100 wipes                    |
| 701000093  | Dentalrapid AF Wipes Neutral, | 1 x refill package with 100 wipes       |
| 701000097  | Dentalrapid AF Wipes Lemon,   | 1 box with 100 wipes                    |
| 701000098  | Dentalrapid AF Wipes Lemon,   | 1 x refill package with 100 wipes       |
| 701000319  | Dentalrapid CD,               | 200 ml foam bottle, empty               |
| 701000310  | Dentalrapid CD,               | 200 ml foam bottle                      |
| 701000531  | Dentalrapid CD,               | 5 liter canister                        |
| 701000241  | Dentafloor,                   | 1 litre metered-dose squeeze bottle     |
| 701000245  | Dentafloor,                   | 5 litre canister                        |
| 701000880  | Dentalrapid AF Technik,       | 500 ml bottle                           |
| 701000588  | Dentalrapid AF Technik,       | 5 litre canister                        |
| 701000181  | Dentasept AF Ultra,           | 1 litre metered-dose squeeze bottle     |
| 701000185  | Dentasept AF Ultra,           | 5 litre canister                        |
| 701000502  | Dentosuc-Spezial 2%,          | 2 litre bottle                          |
| 701000555  | Dentosuc-Spezial 2%,          | 5 litre canister                        |
| 701000615  | Algides Ultra,                | 5 litre canister                        |
| 701000191  | Dentasept AF Plus,            | 1 litre metered-dose squeeze bottle     |
| 701000195  | Dentasept AF Plus,            | 5 litre canister                        |
| 701000402  | Dentodril AF,                 | 2 litre bottle                          |
| 701000400  | Dentodril AF,                 | 5 litre canister                        |
| 701000370  | Dentoderm GEL Sensitive,      | 500 ml Euro-dispenser bottle            |
| 701000371  | Dentoderm GEL Sensitive,      | 1 litre-dispenser bottle                |
| 701000375  | Dentoderm GEL Sensitive,      | 5 litre canister                        |