

**CE Declaration of Conformity  
in accordance with directive 98/79/EC**



We,

MERLIN Gesellschaft für mikrobiologische Diagnostika mbH  
Kleinstraße 14  
53332 Bornheim-Hersel  
Germany

hereby declare in our own responsibility that our products of the product groups

| <b>Product group:</b>                                  | <b>Product:</b> | <b>EDMS-Code</b> |
|--|-----------------|------------------|
| 1. Biochemical Identification / Susceptibility Testing | MICRONAUT-UR    | 14.02.01.09.00   |

Including the following reagents for product group 1:

|                   |                  |
|-------------------|------------------|
| Indole reagent    | for MICRONAUT-UR |
| Peptidase reagent | for MICRONAUT-UR |
| Paraffin oil      | for MICRONAUT-UR |

|                           |              |                |
|---------------------------|--------------|----------------|
| 2. Susceptibility Testing | MICRONAUT-S  | 14.02.01.91.00 |
|                           | MICRONAUT-SB | 14.02.01.91.00 |
|                           | MIC-Strip    | 14.02.05.01.00 |

|                                      |              |                |
|--------------------------------------|--------------|----------------|
| 3. Susceptibility Testing (Mycology) | MICRONAUT-AM | 14.03.06.01.00 |
|--------------------------------------|--------------|----------------|

Including the following reagents:

AST-Indicator and Methylene blue for MICRONAUT-AM

|                        |   |                |
|------------------------|---|----------------|
| 4. Broth Media (Tubes) |   | 14.01.02.01.00 |
|                        | MICRONAUT-SB Medium                         | 14.01.02.01.00 |
|                        | Mueller Hinton broth (CAMHB)                | 14.01.02.01.00 |
|                        | MICRONAUT-H Medium                          | 14.01.02.01.00 |
|                        | MICRONAUT-Wilkins-Chalgren Broth            | 14.01.02.01.00 |
|                        | MICRONAUT-RPMI-1640 Medium + MOPS + Glucose | 14.03.03.01.00 |
|                        | MICRONAUT-ID Medium                         | 14.01.02.01.00 |

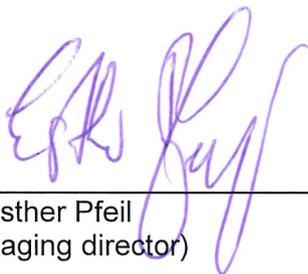
|                              |               |  |
|------------------------------|---------------|--|
| 5. Software for all devices: | MCN6 Software |  |
|------------------------------|---------------|--|

of which this declaration concerns according with the requirements of the conformity assessment procedure of appendix III following the provision of directive 98/79/EC of the council of 27. October 1998 on in vitro diagnostic medical devices. This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Applied harmonized standards: DIN EN ISO 18113, DIN EN 15223-1, DIN EN 13612,  
DIN EN ISO 14971, DIN EN ISO 13485

Valid until: 2022-05-25

Bornheim-Hersel, 2021-09-07  
(Place/date)



\_\_\_\_\_  
Dr. Esther Pfeil  
(Managing director)



\_\_\_\_\_  
Thierry Guillet  
(Managing director)