



Gesellschaft für  
Produktionshygiene und  
Sterilitätssicherung mbH

Talbotstr. 21  
52068 Aachen  
Deutschland / Germany  
phone +49 (0) 241 510050 0  
fax +49 (0) 241 510050 29  
Email: [info@gfps.de](mailto:info@gfps.de)  
<http://www.gfps.de>

# CERTIFICATE FOR THE HYGIENIC INSPECTION OF THE CLEAN ROOMS

FOR THE PURPOSE OF TESTING AND OBSERVATION FOR THE PROOF  
OF THE CONTINUING CONFORMITY WITH THE VALID STANDARDS

for the company

**RAUMEDIC AG**  
**Hermann-Staudinger-Straße 2**  
**95233 Helmbrechts**

On January the 9<sup>th</sup> to 11<sup>th</sup>, 2018, the routine hygienic inspection for the re-qualification of the air-conditioning-system and the clean room "Extrusion SIK – R.156" (measuring points 15601 – 15605) at **RAUMEDIC AG plant Samarium** took place.

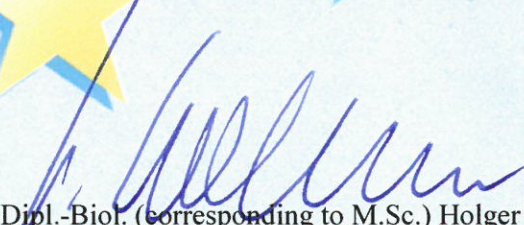
The microbiological contamination of the room air in the clean room "Extrusion SIK – R.156" did not exceed 100 cfu (= colony forming units) per m<sup>3</sup> and corresponded thereby to the request of **GRADE C** of the

### EC GMP Guideline.

The production-hygienic conditions, documented by our measurements, showed comprehensibly that a contamination of the manufacturing goods by the room air of the clean room was nearly not possible.

Aachen, 05/02/18



  
Dipl.-Biol. (corresponding to M.Sc.) Holger Stockem  
Technical Director