DIN EN 16602-70-55:2015-12 (E)

Space product assurance - Microbiological examination of flight hardware and cleanrooms; English version EN 16602-70-55:2015

Inhalt

Seite

Nationaler Anhang NA (informativ) 3

3 Begriffe und Abkürzungen 3
3.1 Begriffe aus anderen Normen 3
3.2 Für diese Norm spezifische Begriffe 3
3.3 Abkürzungen 3

Table of contents

European foreword 4

Introduction 4

1 Scope 6

2 Normative references 7

3 Terms, definitions and abbreviated terms 8

3.1 Terms defined in other standards 8
3.2 Terms specific to the present standard 8
3.3 Abbreviated terms 8

4 Principles 10

5 Requirements 11

5.1 Specifying test 11
5.1.1 General provision 11
5.1.2 Specifying the test means 11
5.1.3 Specifying the test procedure 12
5.2 Validation 13
5.3 Preparing and performing the microbiological examination 13
5.3.1 General 13
5.3.2 Preparing microbiological assays 13
5.3.3 Performing microbiological assays 13
5.3.4 Personnel 14
5.4 Recording and reporting the test results 14
5.4.1 Test records 14
5.4.2 Test report 15
5.4.3 Acceptance criteria and nonconformance 15

Annex A (normative) **Request for microbiological examination - DRD** **16**

Annex B (normative) **Microbiological examination test specifications and procedures (Work Proposal) - DRD** **17**

Annex C (normative) **Microbiological examination test report - DRD** **19**

Annex D (informative) **Procedures for swab assays** **21**

Annex E (informative) **Procedures for wipe assays** **38**

Annex F (informative) **Procedures for contact plates** **56**

Annex G (informative) **Procedure for active air sampling** **58**

Bibliography **60**

Figures

Figure 4-1: Microbiological examination process overview 10

Figure D-1 : Flow chart for the standard swab assay (swab assay 1) 21

Figure D-2 : Flow chart for swab assay 2 24

Figure D-3 : Flow chart for swab assay 3 26

Figure D-4 : Flow chart for swab assay 4 29

Figure D-5 : Flow chart for swab assay 5 (anaerobic conditions from resuspension onwards) 31

Figure E-1 : Flow chart for the standard wipe assay (wipe assay 1) 39

Figure E-2 : Flow chart for wipe assay 2 42

Figure E-3 : Flow chart for wipe assay 3 44

Figure E-4 : Flow chart for wipe assay 4 47

Figure E-5 : Flow chart for wipe assay 5 (anaerobic conditions from resuspension onwards) 50

Tables

Table D-1 : Primers for amplification of 16S rDNA from Archaea, Bacteria and Fungi 35

Table E-1 : Primers for amplification of 16S rDNA from Archaea, Bacteria and Fungi 53