

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