DIN EN 1811:2011-05 (E)

Reference test method for release of nickel from all post as semblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

Contents

Page

Foreword 4

Introduction 5

1 Scope 6

2 Normative references 6

3 Terms and definitions 6

4 Principle of the procedure 7

5 Reagents 7

6 Apparatus 8

7 Samples 9
7.1 Sample area 9
7.1.1 Definition of sample area 9
7.1.2 Determination of sample area 9
7.1.3 Masking of areas other than sample area 9
7.2 Sample degreasing before testing 9
7.3 Quality control samples 9

8 Procedure 10
8.1 Preparation of test solution 10
8.2 Release procedure 10
8.3 Determination of nickel 11
8.3.1 General 11
8.3.2 Calibration solutions 11
8.3.3 Detection limit and quantification limit 11
8.3.4 Number of test samples 11
8.3.5 Number of replicate measurements 11
8.4 Blank tests 11

9 Calculations 11
9.1 Nickel release 11
9.2 Interpretation of results 12
9.2.1 General 12
9.2.2 Assessment of non-compliance 12
9.2.3 Uncertainty budget 13

10 Test report 13

Annex A (informative) Expanded measurement uncertainty of the test procedure and compliance assessment 14

Annex B (normative) Requirements for quality control material 16

Annex C (normative) Requirements for preparation of all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin prior to nickel testing 18

C.1 General 18
C.2 Requirements and principle 18
C.3 Determination of the nickel release test method 18
C.4 Determination of surfaces coming into direct and prolonged contact with the skin or pierced parts of the body 18
C.4.1 Procedures for homogeneous and inhomogeneous articles 18
C.4.2 Jewellery products 20
C.4.3 Other articles such as textiles, footwear, garments, leather goods and mobile phones 25
C.5 Methods of determining the surface areas 26
C.5.1 Surface area measurements 26
C.5.2 Minimum surface area 26
C.5.3 Simplification of surface area determination using common shapes of consumer products 26
C.6 Testing apparatus prior to nickel release testing 26

Annex D (informative) Articles made from composite materials 28

Bibliography 29