DIN EN ISO 13408-2:2011-09 (E)

Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 General requirements 7

5 Selection of filters and filter assemblies based on filter manufacturer's data 7

6 Fluid-specific selection criteria based on filter user's data 7

7 Filtration process 8
7.1 Process parameters 8
7.2 Validation of fluid-specific microbial retention by filters 9

8 Filtration system design 11

9 Routine process 12

10 Process documentation 12

11 Maintenance and change control 13

12 Operator training 13

Annex A (informative) Basic information and quality certificates for filter cartridges 14

Bibliography 18