

DIN EN ISO 16571:2026-11 (E)

Systems for evacuation of plume generated by medical devices (ISO 16571:2024 + Amd 1:2026) (includes Amendment :2026)

Contents

Page

Foreword	iv
▣ Foreword to Amendment 1 ▣	v
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 General requirements	7
4.1 Components	7
4.2 Systems	7
4.3 Capture device	8
4.4 Transfer tubing	9
4.5 Filtration subsystem	9
4.6 Control subsystem	9
4.7 Flow-generator	9
4.8 Exhaust subsystem	10
4.9 Colour coding	10
5 Portable and mobile system requirements	10
5.1 General requirements	10
5.2 Acoustic noise test	10
5.3 Ingress protection	12
6 Stationary and pipeline system requirements	12
6.1 Stationary plume evacuation systems	12
6.2 Design	12
6.3 Flow-generators	13
6.4 Exhausts	13
6.5 Flow-generator controls	13
6.6 Pipeline	14
6.7 Terminal units	14
6.8 Commissioning and testing	14
7 Endoscopic and laparoscopic system requirements	15
7.1 Active PESs	15
7.2 Passive PESs	15
Annex A (informative) Rationale	17
Annex B (informative) Plume evacuation system implementation	20
Annex C (normative) Plume removal efficiency test method	23
Annex D (normative) Colour coding	29
Annex E (normative) Information to be supplied to the healthcare facility	32
Annex F (informative) Acoustic testing muffler design	35
Bibliography	37