

DECLARATION OF CONFORMITY

BECODISC P Stacked Disc Cartridges

BECODISC P stacked disc cartridges are made of depth filter sheets from BECOPAD P range, plastic components and a stainless steel sleeve.

Structure of article numbers: B17162SF

B	171	6	2	S	F
Design	BECOPAD depth filter sheet:	Construction (overall height)¹	Size	Gasket material	Adapter
B = Polypropylene	171 = P 170 271 = P 270 351 = P 350 551 = P 550 581 = P 580	6 = 16 filter cells (10.9/13.0 in) (276/329 mm) 4 = 14 filter cells (10.9/13.0 in) (276/329 mm) 7 = 9 filter cells ² (10.9/13.0 in) (276/329 mm) 9 = 9 filter cells (7.7/10.0 in) (195/248 mm) 5 = 5 filter cells (4.4/6.1 in) (101/155 mm)	2 = 12", Ø 11.6 in (295 mm) 4 = 16", Ø 15.8 in (402 mm)	E = EPDM F = FEP-coated silicone core S = Silicone V = Fluoroelastomer	F = Flat adapter S = Double O-ring adapter Y = Flat adapter with grounding device

¹ Flat adapter/Double O-ring adapter | ² With cell spacer rail

BECODISC P stacked disc cartridges are specially produced for pharmaceutical and biotechnological applications. Therefore the depth filter sheets of BECODISC P stacked disc cartridge is produced with an endotoxin content less than < 0,025 EU/ml. The stacked disc cartridges should be flushed prior to initial use. For special applications, please contact EATON.

Single components and materials:

Depth filter sheet:	Cellulose, wet strength agents
Drainage disc, spacer ring, adapter:	Polypropylene
Cell edge overmould:	Polypropylene
Cell spacer rail: (only version with 9 filter cells (276 / 329 mm))	Polypropylene
Reinforcing ring (only DOR-adapter)	Polyphenyl sulfone
Three-part segmented sleeve, grounding device:	Stainless steel 1.4404, type 316 L
Gasket:	Silicone, EPDM, Fluoroelastomer, Silicon/FEP coated (only FDA)



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BECODISC P stacked disc cartridges are made of materials that correspond to the regulatory and legal requirements and guidelines as follows:

1. BECODISC P stacked disc cartridges meet the requirements for food contact according to Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, in that:
 - 1.1. the depth filter sheets of BECODISC P meet the requirements of German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, LFGB) as well requirements of recommendation XXXVI/1 cooking papers, hot filter papers and filter layers of the Federal Institute for Risk Assessment (BfR),
 - 1.2. the silicone sealings of BECODISC P meet the requirements of recommendation XV and the EPDM and Fluoroelastomer sealings meet the requirements of recommendation XXI of the BfR,
 - 1.3. the plastic components (excluding seals) of BECODISC P stacked disc cartridges meet the requirements of Commission Directive 10/2011/EC and supplements relating to plastic materials and articles in all examination points,
 - 1.4. the stainless steel core and the grounding device of BECODISC P stacked disc cartridges meet the requirements of Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles,
 - 1.5. This product contains materials that are subject to specific migration limits (SML). Migration testings were conducted on BECODISC stacked disc cartridges with the following food simulants with an approach of 6 dm²/L according to Commission Directive 10/2011/EC and supplements:
 - Acetic acid 3 Gew.-% (Simulant B): Duration: 2 hours at 158 °F (70°C)
 - Ethanol, 95-Vol.-% (Simulant D1): Duration: 2 hour at 140°F (60°C)
 - Vegetable oil/ Isooctan (Simulant D2): Duration: 30 min at 104°F (40°C)

The global migration as well as the specific migrations meet the legal requirements upon proper use. BECODISC P stacked disc cartridges can therefore be used to filter foodstuffs without any concerns.



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2. BECODISC P stacked disc cartridges meet the requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.
3. The raw material of construction of BECODISC P stacked disc cartridges as listed below meet the following FDA (Food and Drug Administration) requirements:
 - 3.1. the depth filter sheets according to:
FDA, 21 CFR 177.2260,
 - 3.2. the cellulose and the wet strength agents according to:
FDA, 21 CFR 177.2260 and 21 CFR 177.170,
 - 3.3. the polypropylene according to:
FDA, 21 CFR 177.1520,
 - 3.4. the polyphenyl sulfone according to:
FDA, 21 CFR 176.170(c),
 - 3.5. the silicone, EPDM and Fluoroelastomer sealing materials according to:
FDA, 21 CFR 177.2600,
 - 3.6. the silicone/FEP coated sealing materials according to:
FDA, 21 CFR 177.1550.
4. The depth filter sheets and the polypropylene components of BECODISC P stacked disc cartridges meet the requirements of USP Plastic Class VI – 70 °C (158 °F) test.

Quality Assurance

The quality management system of Eaton Technologies GmbH is certified according to DIN EN ISO 9001.

This declaration expires: 07/2021

Langenlonsheim, 31.07.2018

Eaton Technologies GmbH



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