



**Declaration according to the Medical Device Directive
93/42/EEC article 12**

**Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg
Germany**

declares under his sole responsibility that the products

multiFiltratePRO SecuKits (procedure packs):

- 1. multiFiltratePRO SecuKit Ci-Ca HD 1000 (F00008264)**
- 2. multiFiltratePRO SecuKit Ci-Ca HD EMiC2 (F00008265)**
- 3. multiFiltratePRO SecuKit Ci-Ca HDF 1000 (F00008266)**
- 4. multiFiltratePRO SecuKit Ci-Ca HD 400 (F00008267)**
- 5. multiFiltratePRO SecuKit Ci-Ca HDF 400 (F00008268)**

correspond to the Medical Device Directive 93/42/EEC article 12 and in particular to the 2nd paragraph that deals with systems and procedure packs.

Hereby we confirm:

1. The verification of mutual compatibility of devices which the procedure packs contain (cf. appendix).
2. Every procedure pack contains instructions for use which include relevant instructions from the manufacturer.
3. The manufacture, the control and the documentation of the procedure packs are in accordance with the relevant Standard Operation Procedures System which has been controlled by a complete Quality Management System.

This declaration is solely intended for regulatory purposes.

Sr. Manager QREM EMEA

Name
Sascha Duttiné

Place/Date
Bad Homburg 03.12.2019

Signature



**FRESENIUS
MEDICAL CARE**

**Fresenius Medical Care
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61346 Bad Homburg v.d.H.
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**Appendix
List of articles**

1 multiFiltratePRO SecuKit Ci-Ca HD 1000 (F00008264)

Amount	Article	Material Number	MD class
1	Ultraflux AV1000S	5008981	I Ib
1	multiFiltratePRO SecuCas Ci-Ca HD	F00008116	IIa

2 multiFiltratePRO SecuKit Ci-Ca HD EMiC2 (F00008265)

Amount	Article	Material Number	MD class
1	Ultraflux EMiC2	5009771	I Ib
1	multiFiltratePRO SecuCas Ci-Ca HD	F00008116	IIa

3 multiFiltratePRO SecuKit Ci-Ca HDF 1000 (F00008266)

Amount	Article	Material Number	MD class
1	Ultraflux AV1000S	5008981	I Ib
1	multiFiltratePRO SecuCas Ci-Ca HDF	F00008117	IIa

4 multiFiltratePRO SecuKit Ci-Ca HD 400 (F00008267)

Amount	Article	Material Number	MD class
1	Ultraflux AV400S	5007341	I Ib
1	multiFiltratePRO SecuCas Ci-Ca HD	F00008116	IIa

5 multiFiltratePRO SecuKit Ci-Ca HDF 400 (F00008268)

Amount	Article	Material Number	MD class
1	Ultraflux AV400S	5007341	I Ib
1	multiFiltratePRO SecuCas Ci-Ca HDF	F00008117	IIa