

Addendum for FOX MOBILE Inhalation System IFU DAW-00045 (Rev.06)

9.2 Aerosol characteristics

The Mass Median Aerosol Diameter (MMAD) values presented in section 9.2 (Page 36) are incorrect.

PARTICLE SPECIFICATION	SULTANOL	Скомо HEXAL	ATROVENT
Mass Median Aerosol Diameter (MMAD)	4.91 μm	4.91 pm	4.91 µm

The correct MMAD values are shown below:

PARTICLE SPECIFICATION	SULTANOL	CROMOHEXAL	ATROVENT
Mass Median Aerosol Diameter (MMAD)	4.0 μm ± 0.1	4.0 μm ± 0.1	4.0 µm ± 0.1

12 Explanation of Symbols used

The Medical Devices Regulation (EU) 2017/745 reference presented in Section 12 (Page 47) is incorrect.

12 Explanation of Symbols used

Symbol	Indication
C€	This device compiles with the requirements of the Medical Devices Regulation (EU) 2017/745

The **correct indication** is "This device complies with the requirements of the Medical Devices Directive 93/42/EEC".

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