

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 | CROMO HEXAL | ATROVENT |
|-------------------------------------|----------|-------------|----------|
| Mass Median Aerosol Diameter (MMAD) | 4.91 µm | 4.91 µm | 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 |
|--------|---|
| CE | This device complies 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”.