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MAQUET Cardiopulmonary AG
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To whom it may concern:

This is to confirm that the technical files of the oxygenators with microporous hollow fiber membranes manufactured by Maquet Cardiopulmonary AG and marketed under the product names

Jostra Quadrox
Jostra Safe Mini
Jostra Safe Micro
Polystan Safe Maxi
Polystan Safe Mini
Polystan Safe Micro

with the amended intended use

The Oxygenators are suitable for the transfer of the volatile anaesthetics Isofluran and Sevofluran. The anaesthetics are applied with an adequate vaporizer to the gas inlet of the oxygenator.

meet the requirements of the Medical Device Directive 93/42/EEC, Annex II.

DEKRA Intertek Certification GmbH


Jürgen Bozler

Head of Notified Body for Medical Devices

