

Nova products without Clinical Trial Data

This product range has not been subjected to Clinical trials as defined in Annexe 10 and was placed place on the market prior to the introduction of the CE mark and associated procedures

Placed on the market prior to 1988	YES
Grandfather product	YES
Equivalent to other products on the market	YES

The Oxygen Hood is a small transparent enclosure to allow higher levels of Oxygen to be delivered,

1. Benefit /risk of the devices
Each of these devices was designed in a Hospital department to overcome a specific nursing problem, The greatest risk is overuse and cross infection
2. Equivalence to other devices on the market
There are ranges of Acrylic, and polycarbonate moulded devices,
Full CE Technical file is available
3. Demonstration of acceptability to harmonised standards
4. The “state of the art”
These products are manufactured from sheet Acrylic on a metal frame.
5. Post market surveillance data on device performance
There have been no changes initiated by the user and no reported incidents,
Vigilance reports
6. Registry data
7. Maintenance history
This product range does not require maintenance
8. Sales/marketing feedback
9. User feedback.