Plastic products without Clinical Trial Data   Product

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

This range of devices was originally developed within Special care baby units & Neonatal units to enhance the use of existing equipment
The Oxygen Hood/Headbox is a small transparent enclosure to allow higher levels of Oxygen to be delivered, Originally this was in an incubator but was extended with the introduction of Baby overhead warmers,
The heat shield was used with the headbox to reduce insensible waters
The cotlid was introduced to retain heat in bassinets
The heat shield was used with the headbox to reduce insensible waters
With the introduction of Phototheraphy the Amber Headbox and light shield was introduced to protect the eyes from UV
The ventilation tube holder is an L shaped piece of acrylic with holes for tubes

1. Benefit /risk of the devices
   Each of these devices was designed ina Hospital department to overcome a specific nursing problem, The greatest risk is breakage .
2. Equivalence to other devices on the market
   There are ranges of polycarbonate moulded devices, and disposable devices now available to carry out the same or similar functions
   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. Bent and polished so that there are no rough edges.
5. Post market surveillance data on device performance
   There have been changes initiated by the user and incidents, All covered by the involvement of the MHRA
   The lightshield material was changed to Amber 300 in conjunction with DHSS advice and assistance. NPL results are available.
   The cotlids were changed to prevent them being knocked into the cot
6. Vigilance reports
7. Registry data
8. Maintenance history
   This product range does not require maintenance
9. Sales/marketing feedback
10. User feedback.