

## ANNEX VIII

### STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

#### 3. 3.1.

For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive.]

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;