Status: This is the original version (as it was originally adopted).

## ANNEX II

## **TECHNICAL DOCUMENTATION**

## 5. BENFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

- (a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and
- (b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.