



Via Valletta San Cristoforo 28/10  
17100 SAVONA  
Tel 019/862080  
e-mail: [info@idsdental.it](mailto:info@idsdental.it)  
[www.idsdental.it](http://www.idsdental.it)

## DECLARATION OF CONFORMITY

The undersigned, Legal Representative of “IDS S.p.A.” declares on his own responsibility that the system called:

BLANCONE ULTRA - Code 343010

Category Class I – CND Q010199

Batch xxxx      Expiry date xxxx

Belongs to the category of “**Prophylaxis Materials**” systems.

1. it is classified under risk class I according to rule 5, third point, Attachment IX, Legislative Decree 46/97 and subsequent amendments, integrations and revisions,
2. it is supplied in unsterilized packages,
3. it has been designed and manufactured to produce medical devices which fulfill the essential requirements applicable,

the undersigned declares also that:

4. the applicable essential requirements provided for by Attachment I, Legislative Decree 46/97 and subsequent amendments, integrations and revisions are detailed in section 4 of the system technical file,
5. the systems have been labeled according to the procedure detailed in attachment VII,
6. all manufacturing documents, together with this declaration, are available at IDS Dental for competent authorities and customers,
7. risk analysis and relevant risk management documents have been drawn up according to UNI CEI EN ISO 14971 regulations,
8. the materials comply with UNI EN 1641 and UNI EN ISO 4823 regulations,
9. information supplied with the system has been drawn up according to UNI CEI EN 1041 regulations and the symbols used on the label are in compliance with UNI 980 e ISO 15223-1 regulations,
10. a market surveillance procedure has been established as provided for by Legislative Decree 46/97 and Decree of the Health Ministry dated 15th November 2005,

Date

The Legal Representative