Data gathering form for in vitro diagnostic medical devices (1)
to be used if the subject is authorized representative

Legislative Decree 332 of 8 September 2000:
"Implementation of Directive 98/79/EC concerning in vitro diagnostic medical devices"

1. Tax code (2) ☐

2. Date on which this form is sent ☐

3. Reason for sending this form: (specify relevant item)

3.a First registration of device in Italy ☐

3.b Significant changes to the product ☐

3.c Discontinuation of production on the part of the manufacturer ☐

3.d Device recalled by a competent Authority ☐

4. Communication in accordance with art. 10 c.4

"New" device yes ☐ no ☐

5. Communication in accordance with art. 5 c.2

Device intended to assess performance yes ☐ no ☐

6. Category according to prEN 1874 draft

Code	Description
06	In vitro diagnostic medical devices .

7. Commercial name of device ☐

8. Identification of device type (specify the relevant item, choosing the first one encountered going down the list)

8.a Device of the type included in LIST A of Annex II ☐

8.b Device of the type included in LIST B of Annex II ☐

8.c Device for self-testing (not belonging to Annex II) ☐

8.d Another type of in vitro diagnostic medical device ☐

9. Microbiological status (specify only one of the two items, if necessary)

9.a Sterile device ☐

9.b Device with other microbiological status ☐

10. Information on reagents, reactive products, materials for calibration and control grouped together in terms of common technological properties and/or analytes

Group and type according to EDMA Nomenclature (3)

Code	Name
☐	☐

11. For other in vitro diagnostic medical devices grouped together in terms of appropriate indications (i.e. not reagents, reactive products, materials for calibration and control)

Group and type according to EDMA Nomenclature (4)

Code Name

12. Further information referring to type 8a, 8b and 8c devices as per point 8 above

12.a Compliance checked by a notified body yes ☐ no ☐

12.b Identification number of Notified body

12.c File containing the conformity certificate

12.d File containing the label

12.e File containing the instructions for use

13. Further information referring to type 8a devices as per point 8 above

Conformity with common general technical specifications yes ☐ no ☐

14. Further information referring to type 8a and 8c devices as per point 8 above

Possession of EC examination certificate for the project yes ☐ no ☐

15. Further information referring to devices containing tissues of human origin or substances derived therefrom (Attachment III 3.d)

15.a State of origin

15.b part used **tissues** ☐ **substances** ☐

15.c possession of documentation of origin: **yes** ☐ **no** ☐

Notes

1 Compile a form for each device

2 Specify the same tax code or VAT number or standard coding indicated in the FAB form

3 The code and description of the group of common technological properties and/or analytes referring to the European Diagnostic Manufacturers Association (EDMA) classification

4 The code and description of the group of appropriate indications referring to the European Diagnostic Manufacturers Association (EDMA) classification