

IVDD TECHNICAL FILE

A requirement for the demonstration of compliance with the *IN Vitro* Diagnostics Devices Directive 98/79/EC

Paramedical s.r.l.

DEVICE FAMILY Nome del kit		SECTION RISK ANALYSIS
Section Revision 00	Date Effective: 19/07/2005	Page 1 of 2

RISK ANALYSIS SUMMARY

DEVICE FAMILY: Nome del kit

IVD CATEGORY: GENERAL

That is, the lowest risk IVD category based on the degree of perceived risk (which relates to who a device may be used by, or the effect if it failed to perform as intended).

CONCLUSION

The level of risk from **Paramedical s.r.l.** Nome del kit in terms of an incorrect result being produced for a patient sample is:

LOW

The above conclusion is based on the following sources of information:

- UNI CEI EN ISO 14971:2002
- Risk Analyses
- Safety Data Sheet
- Customer Complaints

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