



**Declaration of Classification for the Sensititre® Product Line**

**To Whom it Concerns**

The Sensititre® Product is composed of reagents and instruments as defined in Directive (98/79/EC). The Sensititre Product Line (IVD) is intended to be use for the examination of specimens, derived from the human body, solely or principally for the purpose of providing information.

**DEVICES COVERED BY THIS DECLARATION:**

Biochemical Identification Automated System(s)  
Susceptibility Testing – Automated System(s)  
Susceptibility Testing – Manual System(s)  
Susceptibility Testing (Mycology) System(s)

System(s) implies a combination of instrument and reagent when necessary

**MANUFACTURER:** TREK Diagnostic Systems  
Imberhorne Lane,  
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United Kingdom

This declaration is valid for all the IVD medical devices described above and which are placed on the market by TREK on or after 1<sup>st</sup> December 2003 and which bear the CE marking.

**AUTHORIZED SIGNATURE:**

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Quality Assurance & Regulatory Affairs Manager  
TREK Diagnostic Systems Ltd.

**Date:** .....*22 July 08*.....