



EC Declaration of Conformity

I, the undersigned, hereby declare that the Product(s)

Biohit Proline tips / Biohit tips

conform with the Essential Requirements listed in Annex I of
EC Directive 98/79/EC (IVD-Directive)

This declaration is supported by EC quality system approval statement (Annex IV)

ISO 9001 / ISO 13485 Certificate No. 97-HEL-AQ-401 issued by DNV on 4 April 2006

ISO 17025 Certificate No. K041/M05/2006 issued by FINAS on 3 March 2006

ISO 14001 Certificate No. 1450-003-AE-HEL-FINAS issued by DNV on 1 March 2006

Signed:

Date: 11.08.2006

Full Name: **Osmo Suovaniemi**

Position: **M.D., Ph.D., Professor**

Title: **President & CEO**

Company: **Biohit Oyj, Laippatie 1, 00880 Helsinki, Finland**

