



DECLARATION OF CONFORMITY

We,

NUNC A/S
Kamstrupvej 90,
DK-4000 Roskilde
Denmark

part of Thermo Fisher Scientific,

hereby declare that the following NUNC CryoTube and NUNC CryoFlask products:

Item no.	Item no.	Item no.	Item no.	Item no.	Item no.	Item no.
333009	348453	363513	366530	373001	375400	377274
336135	355915	363515	366534	373420	375418	379146
337516	363401	363519	366538	373433	375425	379182
339349	363403	363521	366656	373510	375485	379184
340711	363410	363523	367239	373514	376252	379189
347023	363412	363526	368632	373536	377077	
347050	363452	363528	368638	373562	377224	
347595	363479	363531	368716	375299	377262	
347627	363495	363925	368719	375347	377267	
347643	363511	366524	368725	375353	377272	

fulfills the Essential Requirements in Annex I of the EU Directive 98/79/EC.

This declaration is based on the manufacturer's self-declaration rights for a device for *in vitro*-diagnostic purposes, not intended for self-evaluation or any List A or List B applications.

Furthermore, the design and production of the listed products complies with the relevant parts of the DS/EN ISO 13485:2003 including the DS/EN ISO 13485:2003/AC2009.

The notified body, DS Certificering A/S (DGM) – identification no. 0543, has performed an inspection and approved the quality system of NUNC A/S in conformity with the requirements of Annex V, section 3.2 – Production quality assurance, of Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law. Based on the inspection the certificate DGM-693 was subsequently issued, valid from 2010-05-05.

The notified body, QMI-SAI Canada Limited, has performed an inspection and certifies that the Quality Management System of NUNC A/S complies with the requirements of ISO 13485:2003 and subsequently issued the certificates CERT-0044731 (CMDCAS) and CERT-0044732, both valid from 2010-04-05.

Signed for and on behalf of Nunc A/S:

Signature: 
Hans Georg Madsen, QA/RA Director

Date: 2010-12-08
(YYYY-MM-DD)