



Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

AOTI Ltd

**Qualtech House
Parkmore Business Park West
Galway, Co. Galway
Ireland**

to the Product Family

Powered Extremity-oxygenation hyperbaric chamber (Hyper-Box)

GMDN Code: 47189

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorized.*

Registration Number:	252.728
Original Approval:	22 February 2007
Last Amended on:	16 February 2016
Remains valid until:	21 February 2019

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
Susan Murphy
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner .
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**