

UK CA DoC - Rai	manBioConnect™ Probe Product		DOC: QC-153	REV: 1
REVIEWED BY:	Riyan Mohiyuddin	APPROVED BY:	Robert Ashby	May 21, 2025

## **UK CA DECLARATION OF CONFORMITY**

Manufacturer: Tornado Spectral Systems Inc.

5155 Spectrum Way, Unit 6

Mississauga, ON L4W 5A1, Canada.

Obelis Authorized Obelis UK Ltd.

Representative: Sandford Gate, East Point Business Park

OX4 6LB - Oxford

Tel: 44. 1865.910.145 Email: <u>info@obelis.co.uk</u>

Manufacturer declares under its sole responsibility that the product:

## RamanBioConnect™ PROBE

Serial Numbers: 300060-0010 through 300060-9999

is in conformity with the provision of the following Directive:

## **General Product Safety Regulations 2005 (GPSR)**

The product "The RAMANBIOCONNECT™" is intended as an accessory for use with the Tornado Spectral Systems Raman analyzer systems and bioprocess equipment from Sartorius Stedim Biotech. The RAMANBIOCONNECT™ enables real-time measurements of critical analytes and properties of a biopharma mixture.

Conformity assessment was performed according to reg. 5 "general safety requirement" and 6 "Presumption of conformity".

The following standard (s) were used to prove the products conformity with the general safety requirements of the above regulations:

## BS EN ISO 9001:2015

This statement is based on a single evaluation of one sample of the above-mentioned product. It does not imply an assessment of all serial numbers within the product line. The manufacturer shall ensure that all products in this product line are in conformity with the sample detailed in this report.



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Signed for and behalf of Tornado Spectral Systems Inc.

Place	Signature	Date
Mississauga, Ontario	Riyan Mohiyuddin	21-May-2025

Name and Position: Riyan Mohiyuddin, Quality Manager

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Mississauga, ON, L4W 5A1, Canada.