Document Reference:PH-DOC-321Document Issue Number:04Document Issue Date:08/09/2023Page 1 of 11



## **EU Declaration of Conformity**

Manufacturer:	Polyco Healthline Ltd
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Polyco
Product Description:	Vyflex Boa
Product Code:	PF94
PPE Category:	Category III

## It is declared that the above product:

is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 388:2016+A1:2018, EN ISO 21420:2020 and EN 511:2006.

Standard	Performance Levels	
EN ISO 374-1:2016+A1:2018	Type A - AKLMOPT	
EN ISO 374-5:2016	Protection Against Bacteria & Fungi	Protection Against Viruses
	Pass	Not Assessed
EN 388:2016+A1:2018	4131X	
EN 511:2006	121	

- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/10953-05/E05-01, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.
- is subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS Fimko Oy, Takomotie 8, FI-00380, Helsinki, Finland (Notified Body number 0598).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Polyco Healthline Ltd.

Signed for and on behalf of:	Polyco Healthline Ltd
Place and date of issue:	Bourne, 08th September 2023
Name and role:	David Langridge, Head of Technical
Signature:	D Langridge
Expiry Date:	20 <sup>th</sup> May 2026.

Head Office & Distribution Centres: South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK