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Certificate of Compliance

Date	04/11/2025
Product name	VENA® FLEXHOL
Product Prefix	9200882*
Material	VENA TPE FLEXHOL TECH
Manufacturing Location	Venair Biotech SLU: C/ Alguer, 26-28 or C/Perpinya 27 (different entrances of the same building) - 08226 Terrassa (Barcelona) - Spain

Properties	Unit	Inspection Method	Value
Hardness Shore A	Shore A	ISO 868	65
Density	g/cm3	ISO 1183	0.89
Tensile strength	MPA	ISO 37	8
Elongation at break	%	ISO 37	800
Tear Resistance	N/mm	ISO 34-1	28

Certified information

Process	Quality management system certified ISO 9001:2015, ISO 14001:2015, ISO 13485:2016. Produced in ISO7 classified clean room according to ISO14644 in Venair's Spanish manufacturing plant.
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Product	Regulation of the European Parliament and Council (CE) nr. 1935/2004, Commission Regulation (EU) No 10/2011
	U.S. F.D.A. Regulation 21 CFR Part 177.2600
	REACH Annex XIV and XVII
	Restriction of Hazardous Substances (RoHS)

Approval


VENAIR IBÉRICA S.A. U. - TERRASSA (BARCELONA) - ESPAÑA
04/11/2025 11:03:27 UTC

Venair Biotech Quality Department

Venair Ibérica S.A.U.
C/Cerdanya 26, Pol. Ind. Nord – 08226 – Terrassa (Barcelona) - Spain

It is the user's responsibility to ensure the suitability and safety of the VENAIR products for all intended uses. All the tests must be conducted in accordance with applicable regulatory requirements to determine the safety and effectiveness for use of the hoses in any particular application. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. Vena, Venair and the Venair logo are trademarks of Venair Ibérica SA.