



# Indus Medicare Private Limited

CIN.U25209TG1995PTC022254

## EU Declaration of Conformity

Device Identification			
Product Name	Model No. / Brand	UDI - DI	Technical file reference
Natural Rubber Latex Male Condoms	CONDOMZ x 100 CONDOMZ SECONDE PEAU x 100 CONDOMZ BALAISE x 100 CONDOMZ SUR MESURE x 100	890 43812 01046 890 43812 01047 890 43812 01048 890 43812 01049	TF 01
SRN (Single Registration Number):	IN-MF-000008912		
Basic UDI-DI:	89043812MALELATEXCONDOMFU		
EMDN Code:	U110101 - Condoms		
MDN Code:	MDN 1210		
MDS & MDT code(s):	MDT (2004, 2006 & 2011)		
Sterilization Method:	Non sterile		
Device Classification:	Class IIB, Rule 15 as per Annex VIII of EU MDR 2017/745		
Conformity Assessment Route:	Annex IX chapter I & III of EU MDR 2017/745		
Intended Purpose:	Contraception and Prevention of the transmission of sexually transmitted infections		
Manufacturer Name	Address		
Indus Medicare Private Limited	<b>Legal Manufacturer:</b> D. No. 1-10-60/3, Suryodaya, S.P. Road, Begumpet, Hyderabad, Telangana - 500 016, India. Tel: +91 40 2776 2603, Fax: +91 40 2776 1418, E-Mail: <a href="mailto:indusmedicare.hyd@gmail.com">indusmedicare.hyd@gmail.com</a> <b>Manufacturing site:</b> Survey No. 129 (Part), NH 44, Ramaipally Village, Manoharabad Mandal, Medak District, Telangana - 502 336, India. Tel: + 91 79952 20460, E-mail: <a href="mailto:indusrmp@gmail.com">indusrmp@gmail.com</a>		

CRN : 26/23

W.E.F.: 23.08.2023

100 148.0

Page 1 of 3

ISO 9001:2015, NF EN ISO 13485:2016, ISO 13485:2016



ISO 14001:2015

"Suryodaya", 1-10-60/3, Begumpet, Hyderabad-500 016. Telangana, India. Phone: +91 40 27762603, Fax: 91 40 27761418  
**e-mail:** [indusmedicare.hyd@gmail.com](mailto:indusmedicare.hyd@gmail.com) / [indusmedicare2@gmail.com](mailto:indusmedicare2@gmail.com) **website:** [www.indusmedicare.com](http://www.indusmedicare.com)

Factory: Ramaipally (V), Medak Dist.-502 336 Telangana, India. Phone: +91 79952 20460, e-mail: [indusrmp@gmail.com](mailto:indusrmp@gmail.com)



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<b>Authorised EU Representative:</b>	
<b>SRN (Single Registration Number)</b>	NL-AR-000000111
<b>Name</b>	<b>Address</b>
Mr.Ton Pennings	CE partner4U B.V. Esdoornlaan 13, 3951 DB Maarn, The Netherlands. Phone: + 31 343 442 524, Email: <a href="mailto:office@cepartner4u.com">office@cepartner4u.com</a> Website: <a href="http://www.cepartner4u.com">www.cepartner4u.com</a> Tel: +31 343 442 524 Fax: +31 343 442 162 E-mail: <a href="mailto:office@cepartner4u.com">office@cepartner4u.com</a>
<b>Importer</b>	
<b>SRN (Single Registration Number)</b>	NL-IM-000001557
<b>Name</b>	<b>Address</b>
Bizzy Diamond BV	Witboom 1, 4131PL Vianen, The Netherlands TEL : +31 (0)182 796 796 E-Mail: <a href="mailto:ineke@bizzydiamond.com">ineke@bizzydiamond.com</a> Website: <a href="http://www.bizzydiamond.com">www.bizzydiamond.com</a>
<b>Standards Applied:</b>	<b>Harmonized Standards:</b> EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN 62366-1:2015+AC:2015+AC:2016+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 4074:2015, ISO/ TR 20416:2020  <b>Other Standards:</b> ISO 13485:2016, ISO 9001:2015, ISO 14971:2019, ISO/TR 24971:2020, IEC 62366-1:2015+COR 1:2016+ AMD 1:2020, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-23:2021, ISO 15223-1:2021, ISO 20417:2021, ISO 4074:2015, ISO/ TR 20416:2020, ISO 29941:2010, ISO 14001:2015, ISO 2859-1:1999, PMS Guideline, ASTM D5712-15:2020, ASTM D 3492:2024  <b>Guidelines:</b> MEDDEV 2.7.1 Rev. 4:June 2016, MEDDEV 2.5/5 Rev. 3: February 1998, MEDDEV 2.12-1 Rev. 8:January 2013, MEDDEV 2.12/2 Rev. 2:January 2012, NB-MED 2.12/Rec. 1:July 2019, MEDDEV 2.5/9 Rev.1: Feb 2004, MDCG 2021-24:Oct 2021, MDCG 2020-6:2020, MDCG 2018-1 Rev.4:April 2021, MDCG 2020-7:April 2020, MDCG 2020-8:April 2020.

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W.E.F.: 23.08.2023

100 148.0

Page 2 of 3

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Registration Information		
Notified Body ID	CE Certificate Number	Address
2862	No. 28620207089 Issue Date : 31 March 2025 Expiry Date : 30 March 2030	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden Phone: +46 8 750 00 00, Fax: +46 8 750 60 30 Email: <a href="mailto:IMNB@intertek.com">IMNB@intertek.com</a> Website: <a href="http://www.intertek.se">www.intertek.se</a>

**This declaration of conformity is issued under the sole responsibility of Indus Medicare private Limited.**

**We hereby declare that the medical device specified above meets the provision of the Regulation (EU) MDR 2017/745.**

**All supporting documentations are retained at the premises of the manufacturer.**

**Company Representative:**

**Mr. P.J. Reddy**



**Title: Managing Director**

**Signature:**

**Place: Hyderabad**

**Date of issue: 11<sup>th</sup> April, 2025**

**CRN : 26/23**

**W.E.F.: 23.08.2023**

**100 148.0**

**Page 3 of 3**

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