

	EU DECLARATION OF CONFORMITY	
		Document No.: TD.01/2.2 Date of Issue: 15.11.2019 Revision No.: 01 Date of Revision: 02.03.2023

Product Name	Disposable Kidney Tray Disposable Pulp Bedpan Liner Disposable Pulp Urinal Bottle
Company	Viyolsan Paper Packaging Organized Industrial 2nd Zone, 83201st street, No:2 Sehitkamil / Gaziantep / Turkey Post code :27600
Single Registration Number (SRN)	TR-MF-000038737
Article No.	VYL101 VYL201 VYL301
LOT No.	08122023
UDI-DI	8684221569007 8684221569014 8684221569021
CND-Code	V0402 Medical Device – Various / Clinical Trays and Bowels
Class	I
Rule and Explanation	Annex VIII, rule 1 non-invasive
Intended Use	Container for collecting liquids and/or transporting small items
Method of Evaluation	Regulation (EU) 2017/745, Annex IV
Harmonised Standards	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 10993-1 2009/AC:2010, EN ISO 10993-4: 2009, EN ISO 10993-5: 2009, EN 1041:2008, EN ISO 15223-1:2017

Declaration: VIYOLSAN PAPER PACKAGING, whose name, description, product model number, etc. information is mentioned above, declares that the product listed in the appendix carries the CE mark and meets the requirements of the Regulation (EU) 2017/745 (This regulation allows the free movement and sale of the product mentioned above in all European Union countries). All supporting documentation is maintained at the VIYOLSAN PAPER PACKAGING facilities. This Declaration of Conformity identifies that medical devices corresponding to all product model numbers mentioned above are manufactured by VIYOLSAN PAPER PACKAGING and are included in the certified Quality System Documentation. VIYOLSAN PAPER PACKAGING undertakes to fulfill the requirements of the quality system and to maintain the quality system in full and effective. This declaration of conformity is issued under the sole responsibility of legal manufacturer.

Date, Place : 24.01.2024

Signature, Function
BURAK FAKILI
CEO

Viyolsan

Viyolsan Paper Packaging and
Medikal San. Tic. Ltd. Sti.
Organize (Organize OSB) Mahallesi
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