

## EU DECLARATION OF CONFORMITY

Manufacturer: Robert Cullen Limited  
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SRN: NL-AR-000000116

Product range: Disposable Medical Pulp

Product name: Bulbous Urinal

Specification reference: 71787

Basic UDI-DI: 50564746717874A

Intended Purpose: Single use disposable medical pulp. Kitemark for PAS 29 to meet the requirement to hold water and/or human waste for a period of four hours at an initial temperature of 35°C. Suitable for disposal via macerator which complies with the maceration test criteria as stipulated by British Standards Institute (BSI) Product Assessment Specification PAS29:1999.

Classification: Class 1 (According to Annex VIII, Rule 1 of Medical Devices Regulation (EU) 2017/745)

Conformity Assessment Route: Self declaration that the products of this declaration meet the provisions of Medical Devices Regulation (EU) 2017/745

Robert Cullen Limited hereby declares that the above mentioned product meets the provisions of the Medical Devices Regulation (EU) 2017/745

Company Representative: Brian Grassick

Position: HSEQ Manager

Signature: 

Place of issue: Glasgow

Date: 20<sup>th</sup> May 2021

