

EU DECLARATION OF CONFORMITY

Manufacturer:	Curas Sdn. Bhd. (Formerly known as Curas Ltd.(RO)) 69A-B, Raja Uda Business Centre Road 4 12300 Butterworth, Penang Malaysia	
SRN Number:	MY-MF-000036883	
Authorized Representative:	EU Representative Kabomed GmbH Freiheitsstraße 43/1 A-2331 Vösendorf Austria	UK Representative Curas Ltd. County Gates, Ashton Rd. Bristol BS3 2JH England
SRN Number:	AT-AR-000007569	
Basic UDI-DI:	05051400NURXXC	
Medical Device(s):	Hygiene Pulp™ (Disposable Moulded Pulp Products and Supports) All REF numbers as shown in Appendix 1	
Classification:	Class I, according to Annex VIII, Rule 1 of Regulation (EU) 2017/745, repealing Council Directive 93/42/EEC	
Conformity Assessment Route:	Self-declaration that the products meet the provisions Medical Device Regulation (MDR) (EU) 2017/745, repealing Council Directive 93/42/EEC	
Standards Applied:	ISO 9001:2015, Regulation (EU) 2017/745	
Product Standard:	PAS 29:1999	
Notified Body:	SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port Cheshire CH65 3EN UK	
This Declaration of Conformity is issued under the sole responsibility of Curas Sdn. Bhd.		
We hereby declare that the medical device(s) specified above meet the provision of Medical Device Regulation (MDR) (EU) 2017/745 for medical devices.		
All supporting documentation is retained at the premises of the manufacturer and its authorized representative.		
Authorised Signatory:		
Name:	Janice Lim	
Position:	General Manager (Quality Management Representative)	
Place and Date:	Penang, 06 December 2023	

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Appendix 1

List of Curas® Hygiene Pulp™ (Disposable Moulded Pulp Products and Supports)

REF	UDI-DI CODE	Product Description
08000	05051400080005	Disposable Bedpan Liner, 2L, Large, w/Lid, WardPak™
08001	05051400080012	Disposable Slipper (Fracture) Pan Liner, 1.7L, Medium (Midi), w/Lid, WardPak™
08002	05051400080029	Disposable Slipper (Fracture) Pan Liner, 2L, Large (Maxi), WardPak™
08009	05051400080098	Disposable Bedpan Liner, 2L, Large, Non-Pressed, WardPak™
08026	05051400080265	Disposable 2L Bowl w/Hygiene Control Bag™, WardPak™
08027	05051400080272	Disposable 3L Bowl w/Hygiene Control Bag™, Non-Pressed, WardPak™
08028	05051400080289	Disposable 4L Wash Basin w/Hygiene Control Bag™, WardPak™
08030	05051400080302	Disposable 4L Wash Basin, WardPak™
08031	05051400080319	Disposable 1L General Purpose Bowl w/Lid, WardPak™
08032	05051400080326	Disposable 3L General Purpose Bowl w/Lid, WardPak™
08033	05051400080333	Disposable 2L General Purpose Bowl w/Lid, WardPak™
08034	05051400080340	Disposable Jug w/Lid, 1L, WardPak™
08035	05051400080357	Disposable Sampling Cup w/Lid, 200ml, WardPak™
08036	05051400080364	Disposable Ear Irrigation Cup (Noots Tank), 300ml, WardPak™
08040	05051400080401	Disposable Mid-Stream Urine Sampler, 1L, WardPak™
08046	05051400080463	Disposable Ear Irrigation Cup (Noots Tank), w/SAP by Curas™, 300ml, WardPak™
08050	05051400080500	Disposable Urine Bottle, Round, 1L, w/Lid & Stick, Dispensing Carton
08051	05051400080517	Disposable Urine Bottle, Square, 850ml, WardPak™
08052	05051400080524	Disposable Female Urine Bottle, 500ml, WardPak™
08054	05051400080548	Disposable Female Urine Bottle, 500ml, w/ SAP Fluid Absorber Pad, WardPak™
08055	05051400080555	Disposable Urine Bottle, Square, 850ml, Dispensing Carton
08056	05051400080562	Disposable Urine Bottle, Round, 1L, w/SAP by Curas™, Lid & Stick, WardPak™
08057	05051400080579	Disposable Urine Bottle, Round, 1L, w/Lid & Stick, WardPak™
08058	05051400080586	Disposable Urine Bottle, Round, 1L, w/SAP by Curas™ & Lid, RoomPak™
08059	05051400080593	Disposable Urine Bottle, 1.5L, w/Lid, X-Large, WardPak™
08060	05051400080603	Disposable Urine Bottle, 1.5L, w/SAP by Curas™ & Lid, X-Large, WardPak™
08068	05051400080685	Disposable Kidney Tray, 700ml, RoomPak™, Cartonless
08069	05051400080692	Disposable Kidney Tray l BASIC, 700ml, Cartonless

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08070	05051400080708	Disposable Kidney Tray, 700ml, WardPak™
08071	05051400080715	Disposable Kidney Tray, 700ml BASIC
08073	05051400080739	Disposable 1L General Purpose Bowl BASIC
08120	05051400081200	Disposable Lid for Bedpan Liner, WardPak™
08121	05051400081217	Disposable Lid for Midi Slipper Pan Liner, WardPak™
08130	05051400081309	Disposable Lid for 1L General Purpose Bowl, WardPak™
08131	05051400081316	Disposable Lid for 2L General Purpose Bowl, WardPak™
08132	05051400081323	Disposable Lid for 3L General Purpose Bowl, WardPak™
08134	05051400081347	Disposable Lid for 1L Jug, WardPak™
08135	05051400081354	Disposable Lid for Sampling Cup, 200ml, WardPak™
08150	05051400081507	Disposable Lid for Round Urine Bottle, WardPak™
08190	05051400081903	Graduated Stick for Round Urine Bottle, 1L, WardPak™
08202	05051400082023	Disposable Deep Tray, S, 100% Pure Natural Fibre, 18x12.5x3.5cm/7.1x4.9x1.4in, WardPak™
08203	05051400082030	Disposable Deep Tray, M, 100% Pure Natural Fibre, 20.5x12.5x4.5cm/8.1x4.9x1.8in, WardPak™
08204	05051400082047	Disposable Deep Tray, L, 100% Pure Natural Fibre, 27x19x4.5cm/10.6x7.5x1.8in, WardPak™
08233	5051400082337	Disposable Procedure Tray, M, Natural Fibre w/PE, 21.5x13.5x2cm/8.5x5.3x0.8in, WardPak™
08568	05051400085680	Disposable Kidney Tray, 700ml, 100% Natural Fibre, Compostable, RoomPak™
08570	05051400085703	Disposable Kidney Tray, 700ml, 100% Natural Fibre, Compostable, WardPak™
08600	05051400086007	Disposable Round Urine Bottle, 1L, Dispensing Carton BASIC
08602	05051400086021	Disposable Bedpan Liner, 2L, Large BASIC

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