




synthetische Urinal-Kondome


 Konformitätserklärung / Declaration of Conformity /
 Déclaration de Conformité / Dichiarazione di Conformità

Wir,	We,	Nous,	Noi,
Manfred Sauer GmbH, Neurott 7-15, 74931 Lobbach, Germany			
erklären in alleiniger Verantwortung, dass das Medizinprodukt	declare on our own responsibility that the medical device	déclarons sous notre propre responsabilité que le dispositif médical	dichiariamo sotto propria responsabilità che il dispositivo medico
Selbstklebende Urinal-Kondome – SAUER Comfort			
Selbstklebende Urinal-Kondome – SAUER Comfort	Self-adhesive urinary condoms – SAUER Comfort	Etui pénien d'incontinence autocollants – SAUER Comfort	Urinalcondom autocollanti – SAUER Comfort
inklusive der Varianten (falls zutreffend, siehe Beiblatt)	including the variants (if applicable, see enclosed sheet)	inclusive des variantes (le cas échéant, consulter la notice jointe)	Incluse le varianti (se applicabili, vedi supplemento)
allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht.	meets all the provisions of the Directive 93/42/EEC	remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE	adempie a tutte le esigenze della Direttiva 93/42/CEE
Klassifizierung basiert auf den Anforderungen der Regel	Classification is based on the requirements of Rule	Classification est fondée sur les exigences de la Règle	Classificazione basata sui requisiti della regola
1			
des Anhang IX der Richtlinie über Medizinprodukte Medizinprodukt der Klasse	of annex IX of the Medical Device Directive Medical device Class	de l' annexe IX de la directive sur les dispositifs médicaux Dispositif médical Classe	dell' Allegato IX della direttiva sui dispositivi medici Dispositivo medico della classe
I			
Konformitätsbewertungsverfahren gemäß der Richtlinie 93/42/EWG, Anhang	Conformity assessment procedure according to Directive 93/42/EEC, Annex	Procédure d'évaluation de la conformité en application de la directive 93/42/CEE Annex	Procedura di valutazione della conformità secondo la direttiva 93/42/CEE, Allegato
VII			
Benannte Stelle (falls zutreffend)	Notified body (if applicable)	Organisme notifié (le cas échéant)	Organo notificato (se il caso)
-			
Gültig bis	Valid until	Valable jusqu'au	Valida fino al
2021-05-25			
Ort, Datum / Name, Funktion	Place, Date Name, Function	Lieu, Date Nom, Fonction	Luogo, Data Nome, Funzione
Lobbach, 18.05.2020		 Joachim Kaiser Chief Executive Officer	



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Varianten / Variants / Variantes / Varianti		Best.-Nr. / REF
D	SAUER Comfort – Standard	97.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35, 37, 40 mm]
E	SAUER Comfort – Standard	
F	SAUER Comfort – Standard	
I	SAUER Comfort – Standard	
D	SAUER Comfort – Blau	97.7501.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35, 37, 40 mm]
E	SAUER Comfort – Blue	
F	SAUER Comfort – Bleu	
I	SAUER Comfort – Blu	
D	SAUER Comfort – Grün	97.6000.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35, 37, 40 mm]
E	SAUER Comfort – Green	
F	SAUER Comfort – Vert	
I	SAUER Comfort – Verde	
D	SAUER Comfort – Rot	97.6001.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35, 37, 40 mm]
E	SAUER Comfort – Red	
F	SAUER Comfort – Rouge	
I	SAUER Comfort – Rosso	
D	SAUER Comfort – Violett	97.4511.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35 mm]
E	SAUER Comfort – Violet	
F	SAUER Comfort – Violet	
I	SAUER Comfort – Viola	
D	Anti-Allergen	56.xx [xx = Ø 18, 20, 22, 24, 26, 28, 30, 32, 35, 40, 44 mm]
E	Synthetic condoms – Anti-Allergic	
F	Etui pénien synthétique – Hypoallergénique	
I	Condom sintetici – Anallergici	