

MTN Neubrandenburg GmbH
Gustav-Kirchhoff-Straße 2 – 17033 Neubrandenburg

EC-Declaration of Conformity

We,

MTN Neubrandenburg GmbH
Gustav- Kirchhoff- Str. 2
17033 Neubrandenburg
Germany

being, the manufacturer within the European Union of the following dialysis treatment device(s):

Dialysis Concentrates

- **Acid Concentrate for Bicarbonate Dialysis acc. To Product Master II**

- See following articelcode list page 2:


declare that the above mentioned device(s) is/are classified in class IIb, rule 3 and in conformity with the relevant provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, concerning medical devices dated 14 June 1993, Annex I - Essential Requirements -, Annex IX - Classification criteria -, Annex XII - CE marking of conformity -, and our company has been subjected to the procedures laid down in Annex II, section 3.2 full quality assurance system - as certified in our certificate CE 01931 - of the above mentioned directive under the supervision of the British Standards Institution, a Notified Body authorized by the Netherlands B.V, and carrying the Notified Body Number 2797.

This device does not incorporate, as an integral part, a substance as referred to the above-mentioned Directive Annex I section 7.4.

This declaration covered all products of the above-mentioned types.

Neubrandenburg, Germany

Date: 09.03.2022


Irmtraud Steinert
General Manager

**Article code list VI:
Acid Concentrate for Bicarbonate Dialysis
acc. To Product Master II**

		Product- list						
					UDI-DI		UDI-DI	
Type	Description	SAP-Number (Nipro-code)	Article Number- unit of use	GTIN	Article Number- unit of sales	GTIN	Volume	
Product- Master MA II	296	296 A-Concentrate 5 L	AA-296-50C-31	29600050401	4250319514323	29600050431	4250319517102	5 l
		296 A-Concentrate 6 L	AA-296-60C-11	29600060401	4250319514552	29600060411	4250319518482	6 l
		296 A-Concentrate 10 L	AA-296-100C-11	29600100401	4250319516594	29600100411	4250319517539	10 l
	259	259 A-Concentrate 6 L	AA-259-60C-11	25900060401	4250319514613	25900060411	4250319517430	6 l
		259 A-Concentrate 10 L	AA-259-100C-11	25900100401	4250319514767	25900100411	4250319517331	10 l
	757	757 A-Concentrate 10 L	AA-757-100C-11	75700100401	4250319514781	75700100411	4250319517751	10 l
	204	204 A-Concentrate 5 L	AA-204-50C-11	20400050401	4250319514392	20400050011	4250319502009	5 l
		204 A-Concentrate 6 L	AA-204-60C-11	20400060401	4250319514484	20400060011	4250319502399	6 l
		204 A-Concentrate 10 L	AA-204-100C-01	20400100401	4250319514682	20400100001	4250319502795	10 l
	293	293 A-Concentrate 5 L	AA-293-50C-51	29300050401	4250319514224	29300050451	4250319519021	5 l
		293 A-Concentrate 6 L	AA-293-60C-11	29300060401	4250319514538	29300060411	4250319517973	6 l
		293 A-Concentrate 10 L	AA-293-100C-11	29300100401	4250319514798	29300100411	4250319517393	10 l
	761	761 A-Concentrate 5 L	AA-761-50C-31	76100050401	4250319514248	76100050431	4250319517119	5 l
			AA-761-50C-51			76100050451	4250319517126	
		761 A-Concentrate 6 L	AA-761-60C-11	76100060401	4250319514569	76100060411	4250319518604	6 l
			AA-761-60C-31			76100060431	4250319518611	
		761 A-Concentrate 10 L	AA-761-100C-11	76100100401	4250319514750	76100100411	4250319517768	10 l
			AA-761-100C-51			76100100451	4250319517782	
			AA-761-100C-61			76100100461	4250319517775	

		Product- list						
					UDI-DI		UDI-DI	
Type	Description	SAP-Number (Nipro-code)	Article Number- unit of use	GTIN	Article Number- unit of sales	GTIN	Volume	
Product- Master MA II	294	294 A-Concentrate 5 L	AA-294-50C-31	29400050401	4250319514231	29400050431	4250319517089	5 l
			AA-294-50C-51			29400050451	4250319517096	
	294	294 A-Concentrate 6 L	AA-294-60C-11	29400060401	4250319514545	29400060411	4250319518000	6 l
			AA-294-60C-31			29400060431	4250319518475	
		294 A-Concentrate 10 L	AA-294-100C-11			29400100411	4250319517508	
	294	294 A-Concentrate 10 L	AA-294-100C-51	29400100401	4250319514743	29400100451	4250319517522	10 l
			AA-294-100C-61			29400100461	4250319517515	
	248	248 A-Concentrate 5 L	AA-248-50C-41	24800050401	4250319514408	24800050041	4250319800952	5 l
		248 A-Concentrate 6 L	AA-248-60C-11	24800060401	4250319514507	24800060011	4250319502641	6 l
	907	907 A-Concentrate 10 L	AA-907-100C-11	90700100401	4250319518413	90700100411	4250319518055	10 l
	789	789 A-Concentrate 10 L	AA-789-100C-11	78900100401	4250319518284	78900100411	4250319517829	10 l
	987	987 A-Concentrate 6 L	AA-987-60C-11	98700060401	4250319520072	98700060411	4250319520089	6 l
		987 A-Concentrate 10 L	AA-987-100C-11	98700100401	4250319518451	98700100411	4250319518093	10 l
	205	205 A-Concentrate 5 L	AA-205-50C-41	20500050401	4250319514422	20500050041	4250319508056	5 l
		205 A-Concentrate 6 L	AA-205-60C-11	20500060401	4250319514491	20500060011	4250319803977	6 l
		205 A-Concentrate 10 L	AA-205-100C-21	20500100401	4250319514712	20500100021	4250319503600	10 l
			AA-205-100C-31			20500100031	4250319506502	
	262	262 A-Concentrate 6 L	AA-262-60C-11	26200060401	4250319514620	26200060411	4250319517447	6 l
		262 A-Concentrate 10 L	AA-262-100C-11	26200100401	4250319518116	26200100411	4250319517348	10 l
738	738 A-Concentrate 10 L	AA-738-100C-11	73800100401	4250319518222	73800100411	4250319517720	10 l	
750	750 A-Concentrate 10 L	AA-750-100C-11	75000100401	4250319518239	75000100411	4250319517737	10 l	
960	960 A-Concentrate 6 L	AA-960-60C-11	96000060401	4250319517058	96000060411	4250319518710	6 l	
227	227 A-Concentrate 10 L	AA-227-100C-11	22700100401	4250319518109	22700100011	4250319502856	10 l	
283	283 A-Concentrate 6 L	AA-283-60C-11	28300060401	4250319514637	28300060411	4250319517942	6 l	
	283 A-Concentrate 10 L	AA-283-100C-11	28300100401	4250319514774	28300100411	4250319517386	10 l	

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Geschäftsführer: Serge Kemps; Irmtraud Steinert

Commerzbank Neubrandenburg – IBAN DE26 1504 0068 00685 000200, Konto: 0685000200, BLZ 150 400 68

		Product- list						
		SAP-Number (Nipro-code)		Article Number- unit of use	UDI-DI GTIN	Article Number- unit of sales	UDI-DI GTIN	Volume
Type	Description							
Product- Master MA II	257	257 A-Concentrate 5 L	AA-257-50C-51	25700050401	4250319514217	25700050451	4250319517065	5 l
			AA-257-60C-11	25700060401	4250319514514	25700060411	4250319517416	6 l
			AA-257-60C-31			25700060431	4250319519069	
			AA-257-60C-41	25700060441	4250319517423			
	257	257 A-Concentrate 6 L	AA-257-100C-11	25700100401	4250319514729	25700100411	4250319517300	10 l
			AA-257-100C-51			25700100451	4250319517324	
				AA-257-100C-61	25700100461	4250319517317		
				257 A-Concentrate 10 L	AA-266-60C-11	26600060401	4250319514521	26600060411
		266 A-Concentrate 6 L	AA-266-60C-31	26600060431	4250319517492			
	266	266 A-Concentrate 10 L	AA-266-100C-11	26600100401	4250319514736	26600100411	4250319517379	10 l
	788	788 A-Concentrate 10 L	AA-788-100C-11	78800100401	4250319518277	78800100411	4250319517812	10 l
	908	908 A-Concentrate 5 L	AA-908-50C-31	90800050401	4250319514378	90800050431	4250319517157	5 l
		908 A-Concentrate 10 L	AA-908-100C-11	90800100401	4250319518420	90800100411	4250319518062	10 l
	961	961 A-Concentrate 10 L	AA-961-100C-11	96100100401	4250319518444	96100100411	4250319518086	10 l
	286	286 A-Concentrate 6 L	AA-286-60C-11	28600060401	4250319517959	28600060411	4250319517966	6 l
	263	263 A-Concentrate 6 L	AA-263-60C-11	26300060401	4250319514644	26300060411	4250319517454	6 l
		263 A-Concentrate 10 L	AA-263-100C-11	26300100401	4250319518123	26300100411	4250319517355	10 l
	787	787 A-Concentrate 6 L	AA-787-60C-11	78700060401	4250319517003	78700060411	4250319518628	6 l
		787 A-Concentrate 10 L	AA-787-100C-11	78700100401	4250319518260	78700100411	4250319517805	10 l
	265	265 A-Concentrate 6 L	AA-265-60C-11	26500060401	4250319517461	26500060411	4250319517478	6 l
265 A-Concentrate 10 L		AA-265-100C-11	26500100401	4250319518130	26500100411	4250319517362	10 l	
909	909 A-Concentrate 5 L	AA-909-50C-31	90900050401	4250319514385	90900050431	4250319517164	5 l	
	909 A-Concentrate 10 L	AA-909-100C-11	90900100401	4250319518437	90900100411	4250319518079	10 l	