

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE / DICLARATIONE DE CONFORMITA

Wir / We / Nous /Noi

Name + Adresse der Firma / Name + address of manufacturer /
Nom + adresse de l'entreprise / Nome + indirizzo della ditta :

Dr. J. Hänsler GmbH, Nordring 8, D - 76473 Iffezheim, Germany

erklären in alleiniger Verantwortung, dass

declare on our own responsibility that
déclarons sous notre propre responsabilité que
dichiaramo sotto propria responsabilità che

das Medizinprodukt / the medical device / le dispositif mé dical / il dispositivo medico

Name / name / nom / nome

OZONOSAN

**alpha plus / photonik / boardcase / cytozon
Vacuum bottles / germ stop**

Typ / type or model /

type ou modèle / tipo o modello

XXXX (see attached list)

SN:

XX XXX XX (SN will be added after manufacturing)

allen Anforderungen der Richtlinie 93/42/EWG (Anhang I) entspricht.

meets all the provisions of the Directive 93/42/EEC (annex I) which apply to him.
remplit toutes les exigences de la 93/42/CEE (annexe I) qui le concerne.
addeempie a tutte le esigenze della Direttiva 93/42/CEE che lo riguardano.

Benannte Stelle:

Notified body
Organisme notifié
Organo notificato

**TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65
80339 München Germany**

CE 0123

Iffezheim, Oct. 12. 2020

(Datum)



Robert Viebahn
Managing Director

List of products

Name or identification of the medical device and / or accessories	Variant	Item no	UMDNS Code	Class	93/42/EEC MDD	sterile	
						Yes	No
OZONOSAN alpha plus	Ozone generator + Photometer	1107	12-899	Ila	93/42/EWG		X
	Ozone generator + Photometer + Ozone-water	1087	12-899	Ila	93/42/EWG		X
	Ozone generator + Photometer + Suction	1097	12-899	Ila	93/42/EWG		X
	Ozone generator + Photometer + Suction + Ozone-water	1007	12-899	Ila	93/42/EWG		X
OZONOSAN photonik	Ozone generator + Photometer	1010	12-899	Ila	93/42/EWG		X
	Ozone generator + Photometer + Suction + Flowmeter	1016	12-899	Ila	93/42/EWG		X
OZONOSAN boardcase	Portabel – Ozone generator + Photometer + Suction	1080	12-899	Ila	93/42/EWG		X
	Portabel – Ozone generator + Photometer	1080.1	12-899	Ila	93/42/EWG		X
OZONOSAN cytozon	Ozone generator + Ozone-water	1017	12-899	Ila	93/42/EWG		X
OZONOSAN Vacuum bottles	250ml Mikro Perl System (MPS) + 12 ml Na-Citrat	3202	15-809	IIb	93/42/EWG	X	
	250ml Mikro Perl System (MPS)	3200	15-809	Ila	93/42/EWG	X	
OZONOSAN Germ stop	Ozone perfusionssystem	3035	11-712	Ila	93/42/EWG	X	