

DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	BRAND NAME	PACKAGING	Classification	Rule
D5K10S	HI-TRAY METAL	Kit of 10 upper and lower trays solid (5 + 5)	Class I	Rule 5
D5K08S	HI-TRAY METAL	Kit of 8 upper and lower trays solid (4 + 4)	Class I	Rule 5
D5K10P	HI-TRAY METAL	Kit of 10 upper and lower trays perforated (5 + 5)	Class I	Rule 5
D5K08P	HI-TRAY METAL	Kit of 10 upper and lower trays perforated (4+ 4)	Class I	Rule 5
D51SS	HI-TRAY METAL	Upper solid tray no. 1	Class I	Rule 5
D52SS	HI-TRAY METAL	Upper solid tray no. 2	Class I	Rule 5
D53SS	HI-TRAY METAL	Upper solid tray no. 3	Class I	Rule 5
D54SS	HI-TRAY METAL	Upper solid tray no. 4	Class I	Rule 5
D55SS	HI-TRAY METAL	Upper solid tray no. 5	Class I	Rule 5
D51IS	HI-TRAY METAL	Lower solid tray no.1	Class I	Rule 5
D52IS	HI-TRAY METAL	Lower solid tray no.2	Class I	Rule 5
D53IS	HI-TRAY METAL	Lower solid tray no.3	Class I	Rule 5
D54IS	HI-TRAY METAL	Lower solid tray no.4	Class I	Rule 5
D55IS	HI-TRAY METAL	Lower solid tray no.5	Class I	Rule 5
D51SP	HI-TRAY METAL	Upper perforated tray no. 1	Class I	Rule 5
D52SP	HI-TRAY METAL	Upper perforated tray no. 2	Class I	Rule 5
D53SP	HI-TRAY METAL	Upper perforated tray no. 3	Class I	Rule 5
D54SP	HI-TRAY METAL	Upper perforated tray no. 4	Class I	Rule 5
D55SP	HI-TRAY METAL	Upper perforated tray no. 5	Class I	Rule 5
D51IP	HI-TRAY METAL	Lower perforated tray no. 1	Class I	Rule 5
D52IP	HI-TRAY METAL	Lower perforated tray no. 2	Class I	Rule 5
D53IP	HI-TRAY METAL	Lower perforated tray no. 3	Class I	Rule 5
D54IP	HI-TRAY METAL	Lower perforated tray no. 4	Class I	Rule 5
D55IP	HI-TRAY METAL	Lower perforated tray no. 5	Class I	Rule 5
D5CSUP	HI-TRAY LIGHT CLEAR	Small Upper 12 pcs	Class I	Rule 5
D5CMUP	HI-TRAY LIGHT CLEAR	Medium Upper 12 pcs	Class I	Rule 5
D5CLUP	HI-TRAY LIGHT CLEAR	Large Upper 12 pcs	Class I	Rule 5
D5CSLO	HI-TRAY LIGHT CLEAR	Small Lower 12 pcs	Class I	Rule 5
D5CMLO	HI-TRAY LIGHT CLEAR	Medium Lower 12 pcs	Class I	Rule 5
D5CLLO	HI-TRAY LIGHT CLEAR	Large Lower 12 pcs	Class I	Rule 5
D5GSUP	HI-TRAY LIGHT PLASTIC	Small Upper 12 pcs	Class I	Rule 5
D5GMUP	HI-TRAY LIGHT PLASTIC	Medium Upper 12 pcs	Class I	Rule 5
D5GLUP	HI-TRAY LIGHT PLASTIC	Large Upper 12 pcs	Class I	Rule 5
D5GSLO	HI-TRAY LIGHT PLASTIC	Small Lower 12 pcs	Class I	Rule 5
D5GMLO	HI-TRAY LIGHT PLASTIC	Medium Lower 12 pcs	Class I	Rule 5
D5GLLO	HI-TRAY LIGHT PLASTIC	Large Lower 12 pcs	Class I	Rule 5
D5ESUP	HI-TRAY LIGHT EDENTULOUS	Small Upper 12 pcs	Class I	Rule 5
D5EMUP	HI-TRAY LIGHT EDENTULOUS	Medium Upper 12 pcs	Class I	Rule 5
D5ELUP	HI-TRAY LIGHT EDENTULOUS	Large Upper 12 pcs	Class I	Rule 5
D5ESLO	HI-TRAY LIGHT EDENTULOUS	Small Lower 12 pcs	Class I	Rule 5
D5EMLO	HI-TRAY LIGHT EDENTULOUS	Medium Lower 12 pcs	Class I	Rule 5

D5ELLO	HI-TRAY LIGHT EDENTULOUS	Large Lower 12 pcs	Class I	Rule 5
D5DANT	HI-TRAY LIGHT DUAL ARCH	Anterior 30 pcs	Class I	Rule 5
D5DFUL	HI-TRAY LIGHT DUAL ARCH	Full Arch 30 pcs	Class I	Rule 5
D5DPOS	HI-TRAY LIGHT DUAL ARCH	Posterior 48 pcs	Class I	Rule 5
D5DPLE	HI-TRAY LIGHT DUAL ARCH	Posterior Sideless 48 pcs	Class I	Rule 5
D5DQUA	HI-TRAY LIGHT DUAL ARCH	Quadrant 40 pcs	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIREECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEXES I, VII, X, XII. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DEDECLARATION OF CONFORMITY.				
Harmonized Standards applied:		UNI EN ISO 13485: 2016 UNI CEI EN ISO 14971: 2012 UNI CEI EN 1041: 2013 ISO 15223-1: 2016		
Technical standards ref.:		/		
EC certificate :		Not applicable		

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 Barbara Baruzzo
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Badia Polesine, 29.11.2018