



EU Declaration of Conformity

Manufacturer

Name R82 A/S
Address of registered place of business Parallelvej 3
8751 Gedved
Denmark
SRN N/A

This EU declaration of conformity is issued under the sole responsibility of the manufacturer

Basic UDI-DI N/A

Product / device

Name Scallop
Size 1, 2, 3, 4
Intended purpose Portable seat for disabled children

Risk class of the device Class 1

The device covered by present declaration is in conformity with Council directive 93/42/EEC on medical devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Reference to Common Specifications used and in relation to which conformity is declared

Standard	ISO 14971:2012	Medical Devices Application of risk management to medical devices
	ISO 16840-3:2014 Section 7.5	Wheelchair seating Part 3: Determination of static impact and repetitive load strengths for postural support devices
	ISO 10993-5:2009	Biological evaluation of medical devices Part 5: test for cytotoxicity
	ISO 1021-1:2014	Furniture – Assessment of ignitability of upholstered furniture Part 1: Ignition source smouldering cigarette
	ISO 1021-2:2014	Furniture – Assessment of the ignitability of upholstered furniture Part 2: Ignition source match flame equivalent
	ISO 7176-16:2012	Wheelchairs Part 15: Resistance to ignition of postural support devices

Place Gedved
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Name and function


Ulla Lange/Director of Quality and Regulatory Affairs