

Wheelchairs powered by

SOFTWHEEL



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Introducing the NEW

SOFTWHEEL

3



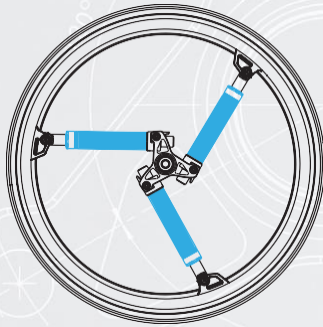


**SoftWheel's innovative
in-wheel suspension technology
can help reduce pain and
provide a more comfortable ride**



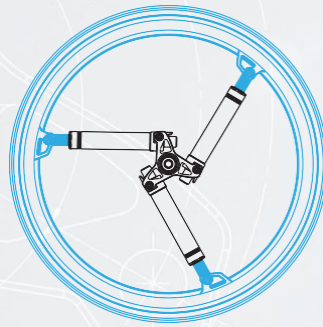
For more info visit www.49bespoke.com

Patented In-Wheel Suspension System



In-Wheel Suspension

3 suspension arms are built inside the wheel and compress to absorb shocks



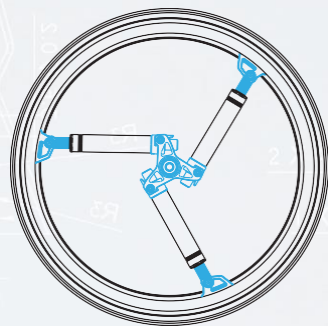
Rigid Rim

Wheel rim is always rigid & strong, while the suspension arms & hub compress to provide shock absorption



Automatic Actuation

Suspension arms automatically compress when encountering an obstacle or rough terrain, and remain rigid & strong over flat surfaces



360° Suspension

Arms are set equidistant around a central hub to provide shock absorption - no matter the angle of impact



Rapid Shock Reset

Suspension arms immediately reset and return the wheelchair - and rider, to a level ride

SoftWheel Features

SGFTWHEEL



Dual system suspension with high & low frequencies

Silent mechanism

Quick axle release

IP55: protected from dust & water

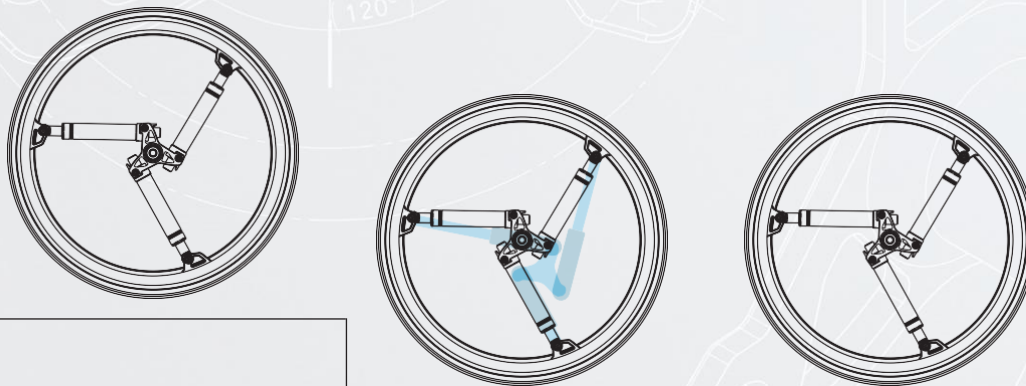
Slim rim with lighter design

Anodized aerospace aluminum

Shock Absorption That Actuates Only When You Need It

The wheel rim always remains rigid, while the suspension arms & hub shift to provide shock absorption only when needed – when encountering an obstacle or rough terrain.

This leads to a smoother, more efficient ride over all types of terrain.



SOFTWHEEL





For more info visit www.49bespoke.com

Whole body vibrations are a health concern for wheelchair riders

01

Long-term exposure to vibrations has been demonstrated to have a negative impact on people's health & comfort

02

Clinical studies have shown that wheelchair riders are exposed to vibrations that exceed the recommended exposure limits

03

Health risks associated with vibrations for wheelchair riders include lower back pain, effects on the spine, and muscle fatigue

References:

"Health risks of vibration exposure to wheelchair users in the community," Garcia-Mendez Y, Pearlman J, Boninger ML, Cooper RA;
The Journal of Spinal Cord Medicine **2013 Jul; 36(4):365-375**

"Analysis of vibrations induced during wheelchair propulsion," VanSickle DP, Cooper RA, Boninger ML, DiGiovine CP;
Journal of Rehabilitation Research and Development **2001 Jul-Aug; 38 (4):409-421**

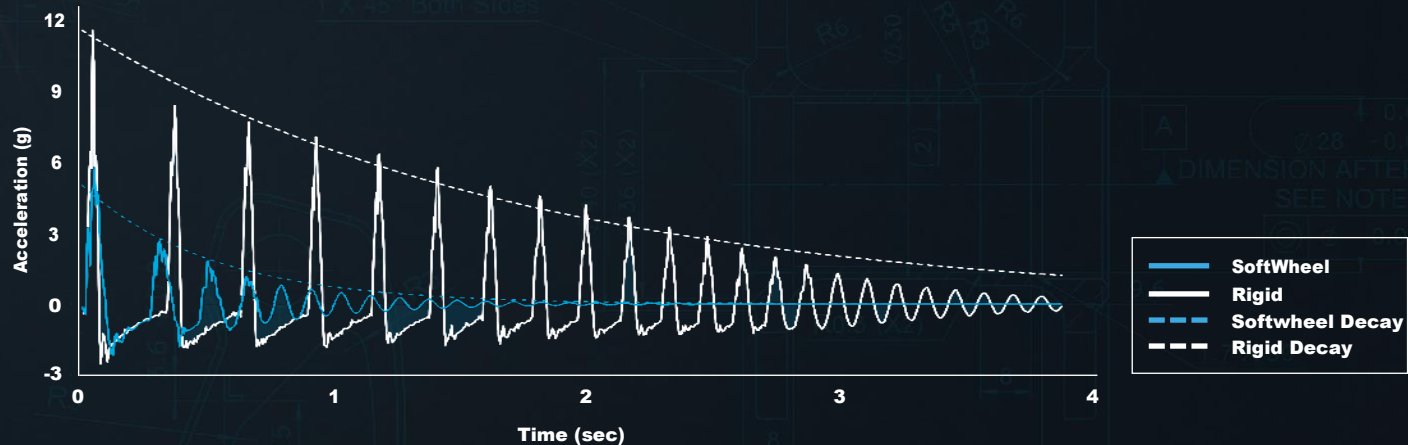
SoftWheel Reduces Vibrations

SGFTWHEEL

The innovative suspension & damping technology disperses the impact energy, thereby shortening the impact duration and shock magnitude transferred to the rider

Fewer vibrations are therefore transmitted to the rider, leading to a smoother, more comfortable ride

SoftWheels are more energy efficient, helping to maintain forward momentum, which can reduce fatigue



**Drop Test from 15 cm (standard curb height)
SoftWheel vs. Standard Rigid Wheel: Acceleration Over Time**

A woman with blonde hair, wearing a black t-shirt with three stars, is sitting in a black Softwheel wheelchair in a supermarket aisle. She is holding a bag of vegetables. The aisle is filled with shelves of various products, including fresh produce like bananas, oranges, and leafy greens on the left, and packaged goods on the right. The floor is light-colored tile. The background shows more shelves and a bright, well-lit environment. The text "Why do wheelchair riders need suspension?" is overlaid in white, bold font. The Softwheel logo is in the bottom left corner.

Why do wheelchair riders need suspension?

SOFTWHEEL

HEALTH



Can help reduce back & neck pain, and decrease fatigue at the end of the day

SAFETY



Keeps the rider steady while going over bumps and remains stable & rigid over flat terrain

COMFORT



Absorbs shock & vibrations on all types of terrain, providing maximum cushioning

A group of four people, two men and two women, are sitting in wheelchairs on a wooden deck in front of a house. They are engaged in conversation. A large, fluffy dog is lying on the deck in the foreground. The scene is outdoors, with a brown door and a large window visible in the background. The text 'SoftWheel meets the daily needs of wheelchair riders' is overlaid in white.

SoftWheel meets the daily needs of wheelchair riders

SOFTWHEEL

Can provide riders with:

#01

Less Pain

1" X 45" Both Sides

#02

**Greater
Comfort**

#03

**Increased
Independence**

#04

**Better Outdoor
Mobility**

For more info visit www.49bespoke.com



**Clinical research shows
SoftWheel helps improve
health, safety, and comfort**

SOFTWHEEL

**“In general, I hardly
felt vibrations
while riding”**



**“I feel very secure
while riding the
wheelchair”**



**“I feel it was easy &
comfortable to propel
on uneven terrain”**



Source: Clinical Trial 2017, Emek Medical Center

For more info visit www.49bespoke.com



**Softwheel makes a real
difference in people's lives**

SOFTWHEEL



“I had immediate relief from lower back pain after switching to SoftWheels”

Kimberly



“For me, SoftWheels are freedom”

David



“Since I’ve started using SoftWheels, I don’t feel any pain”

Nataly

For more info visit www.49bespoke.com



Review my
Wheelchair

9.5

AMAZING

“A Significant Ride Improvement”

“Soft-riding is a breeze, moving over rougher ground without any significant sudden jolts...

It reduces the impact transferred from frame to spine...

SoftWheels offer a working professional a significant ride improvement.”

**Review My Wheelchair
April 2018**

SOFTWHEEL





“A Softer Ride”

“A pretty impressive feat of engineering...

the ride did become noticeably softer. All the bumps, cracks and drops on my daily pushing routes were noticeable smoothed...

By switching wheels, my chair felt like it had built-in suspension.”

**New Mobility
November 2018**



For more info visit www.49bespoke.com

Certifications



The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (add individual products within an existing generic group)
- discontinuation of a generic group of devices

Please use FD2, the Registration form, to tell us about any of these changes.
Thank you for registering the following generic groups of devices:

Class / Device:
Wheelchairs (Non-Powered) And Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect in-Vitro Diagnostic devices registration, which remain confidentially under Article 13 of the In-Vitro Diagnostic Directive 98/79/EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely



Sean Williams
Regulatory Affairs Officer
Tel: 0203 986 7323
Email: sean.williams@mhra.gov.uk

Confidentiality 3 Sept 2009

CE Certificate

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., W066 Room 2621
Silver Spring, Maryland 20993-0002

April 7, 2015

Dear Sir or Madam,

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) received registration and listing information identifying you as the Official Correspondent for the medical device facility listed below. Please keep this confirmation email and any attachments for your records.

Establishment Name: SOFTWHEEL LTD.
Establishment Address: 24 RAOUL WALLENBERG
TEL AVIV, TEL-AVIV 6971920
ISRAEL

PR/PCN Details:
PR# 30138209 PCN 1526488

If you have any questions or need assistance, please e-mail CDRH Registration and Listing at reglist@cdrh.fda.gov, or call (301) 796-7300, Monday through Friday, between 8:00 am and 5:00 pm ET.
CDRH Registration and Listing Office

FDA – Class 1


Product Service
Class certificate
Add value

Technical Report No. 713105340
Revision: 0
dated 2017-09-19

Client: SoftWheel Ltd.
Raul Wallenberg St. 24
IL-0671920-Tel Aviv

Manufacturing place: SoftWheel Ltd.
Raul Wallenberg St. 24
IL-0671920-Tel Aviv

Test object: Drive wheel with hand rim for manual wheelchairs
Type: Acrobati A
max. load: 145 kg (wheelchair with patient)

Test specifications: EN 12183:2014, section 7.2
- ISO 7176-8:1996, section 8.4, 10.4 and 10.5

Testing according to the test specifications.

Purpose of certification: The test results show that the presented product is in compliance with the specified requirements.

Test result:

This technical report may only be quoted in full. Any use for advertising purposes must be granted in writing. This report is the result of a single examination of the object it certifies and is in no way a general production of the quality of other products in regular production.

PR 713105340-001
Ref.: 713105340
Rev.: 01
Page 1 of 1

Product Manager
certified
Date: 2017-09-19

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TUV

TUV SUD Product Service (GmbH)
Rheinland-Str. 1
51105 Köln
Germany

TÜV SÜD



For more info visit www.49bespoke.com

**For maximum performance,
SoftWheel is available in 4 stages,
customized to a rider's weight**

Stage	Weight (kg)	Weight (lbs.)
A	up to 50kg	up to 110 lbs.
B	50 - 70kg	110 - 155 lbs.
C	70 - 90 kg	155 - 200 lbs.
D	90 - 136 kg	200 - 300 lbs.

Size: 24" & 25"

Hub: AL 6061 T6; high precision CNC

Rim: AL 6061 T6

Bearing diameter: U.S. or

European standard

Load limit: 136 kg (300 lbs.)

Wheel weight: 1.8 kg (4 lbs.)

Drum Brake: Optional



For more info visit www.49bespoke.com

100.0.0.11

SOFTWHEEL
Wheel Reinvented



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